CERTIFICATE OF TRANSMITTAL I hereby certify that on **September 4, 2008**, this paper (along with any paper referred to as being attached or enclosed) is being transmitted through the EFS system via the United States Patent and Trademark Office website at http://www.uspto.gov. Kathy Hinckley

PATENT

Applicant:	Brian J. Cox
Serial No.:	10/763,975
Filed:	January 22, 2004
Title:	**ANEURYSM TREATMENT DEVICE AND METHOD OF USE**
Examiner:	Severson, Ryan J.
Group Art Unit:	3731
Confirmation No.:	7891
Atty. Docket No.:	388700-58B

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BOARD OF PATENT APPEALS AND INTERFERENCES

APPEAL BRIEF UNDER 37 CFR § 41.37

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the Final Office Action mailed February 21, 2008 ("*Final Office Action*") (Attached as Exhibit 1), please consider the Appeal Brief contained herein. It is believed that this Appeal Brief addresses all outstanding issues; that entry of this Appeal Brief is proper; and that the preparation and mailing of an Examiner's Answer is now in order.

The Commissioner is hereby authorized to charge payment of the $510.00 fee for filing of this Appeal Brief to the credit card specified during the EFS process. The Commissioner is authorized to charge any additional filing fees or credit any overpayment to Deposit Account No. 50-2809.

REAL PARTY IN INTEREST

The real party in interest is MicroVention, Inc., a Delaware corporation having a place of business at 75 Columbia, Suite A, Aliso Viejo, CA 92656. MicroVention, Inc. is the Assignee of all rights in the application.

RELATED APPEALS AND INTERFERENCES

There are currently no appeals or interferences known to the Appellant, the appellant's legal representative, or assignee which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

STATUS OF CLAIMS

Claims 23-28, 40, and 41 are currently pending. Claims 29-39, 42, and 43 were previously withdrawn from consideration, and claims 1-22 were previously canceled. Claims 23-28, 40, and 41 stand rejected and are currently under appeal.

STATUS OF AMENDMENTS

In the Amendment filed on May 21, 2008 in response to the *Final Office Action,* new claims 44 and 45 were introduced. These claims were not entered, as explained in the Advisory Action mailed June 10, 2008 ("*Advisory Action*") (Attached as Exhibit 2). The claims as they are currently entered are presented in the Appendix of this document.

SUMMARY OF CLAIMED SUBJECT MATTER

The claims presently under appeal are claims 23-28, 40, and 41. Claims 23 and 40 are independent claims. Claims 24-28 depend from claim 23 or a dependant claim that depends from claim 23, and claim 41 depends form claim 40.

In accordance with 37 C.F.R. 41.37(c)(1)(v) the subject matter of independent claims 23 and 40 is concisely explained below. It is believed that none of these independent claims invokes means plus function or step plus function treatment under 35 U.S.C. § 112 ¶ 6.

The subject matter as defined in independent claim 23 relates to an apparatus for treating vascular aneurysms. Application No. 10/763,975 as filed (Attached as Exhibit 3) at p. 20, lines 5-6 (¶ 0075) and FIGS. 10-12. Specifically, the apparatus (40) includes a support structure (42) sized for placement at a region of the vascular aneurysm (10). *Id.* at p. 20, lines 6-13 (¶ 0075), and FIGS. 10-12. As seen best in FIG. 12, the support structure (42) includes a bridge portion spanning at least a neck region of the vascular aneurysm (10). *Id.* The support structure (42) has an open, non-tubular arced (46) configuration. *Id.* at p. 20, lines 8-9 (¶ 0075), and FIGS. 10 and 11. The bridge portion further includes a reactive material, the reactive material being expanded when in a reacted state such that the reactive material restricts flow of blood to the vascular aneurysm when the reactive material is in the reacted state. *Id.* at p. 20, lines 15-19 (¶ 0075), and FIGS. 10-12.

The subject matter as defined in claim 40 involved in this appeal relates to an implant for treating a vascular aneurysm. *Id.* at p. 20, lines 5-9 (¶ 0075), and FIGS. 10-12. More specifically, the implant (40) includes an implant body (42) sized to reside at a region of a vascular aneurysm. *Id.* at p. 20, lines 6-13 (¶ 0075), and FIGS. 10-12. As seen best in FIG. 12, the implant body has an occlusion region that substantially traverses a neck region of the vascular aneurysm. *Id.* The implant body (42) has an arc (46) shape, said arc (46) shape having a sweep less than 360 degrees. *Id.* at p. 20, lines 8-9 (¶ 0075), and FIGS. 10 and 11. The occlusion region including a reactive material, the reactive material being expanded when in a reacted state such that the occlusion region substantially restricts flow of blood to the vascular aneurysm when the reactive material is in a reacted state. *Id.* at p. 20, lines 15-19 (¶ 0075), and FIGS. 10-12.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Whether claims 23-28, 40, and 41 of the present application are unpatentable under 35 U.S.C. §103(a) over U.S. Patent No. 6,231,597 to Deem et al. in view of U.S. Patent No. 5,234,456 to Silvestrini.

ARGUMENT

I. REJECTION OF CLAIMS 23 AND 40 UNDER 35 U.S.C. §103(a)

In the *Final Office Action,* claims 23-28, 40, and 41 were rejected under 35 U.S.C. §103(a) as being rendered obvious over U.S. Patent No. 6,231,597 to Deem et al. ("*Deem et al.*") (Attached as Exhibit 4) in view of U.S. Patent No. 5,234,456 to Silvestrini ("*Silvestrini*") (Attached as Exhibit 5). Of the pending claims, claims 24-28 depend from claim 23 or a dependent claim that depends from claim 23, and claim 41 depends form claim 40.

The Examiner contends that *Deem et al.* teach all the elements of the claimed invention with the exception that *Deem et al.* do not teach a reactive material that expands when in a reacted state. *Final Office Action* at p. 2, line 14 through p.3, line 20. *Deem et al.* disclose stents and delivery systems used for treatment of vascular aneurysms. At p. 7, column 1, lines 6-10. As illustrated in FIG. 4 and discussed at p.9, column 5, lines 45-49, the stent 101 of *Deem et al.* includes cover 102 that is disposed about a portion of the circumference of stent 101 and spans elements 14 of stent 101. *Deem et al.* teach that cover 102 may comprise a typical graft material, such as polyester or PTFE. At p.9, column 5, lines 49-52. When stent 101 is deployed in the vessel of a patient, cover 102 is oriented to span the abnormality to promote clotting and endothelial growth. *Id.* at p.9, column 5, lines 53-55.

To overcome the deficiency of *Deem et al.* to teach or make obvious the claimed reactive material being expanded when in a reacted state such that the reactive material restricts flow of blood to the vascular aneurysm when the reactive material is in the

reacted state, the Examiner relies upon *Silvestrini*. *Silvestrini* discloses several tubular stent embodiments intended for maintaining a body lumen, such as a vessel, in an open configuration. At p. 2, column 1, lines 8-11, and FIGS. 1-4. In each of the embodiments, *Silvestrini* teaches that the entire stent or a portion of the stent is constructed of a balloon or hollow fibers made from semi-permeable membrane that is filled with an expandable, hydrophilic material. At p. 3, column 2, lines 26-42; p. 4, column 3, lines 29-52; and p. 3, column 4, lines 16-32. In the embodiment illustrated in FIG. 3, the embodiment relied upon and cited by the Examiner, the tubular stent 40 is constructed so that a potion of the wall 44 comprises hollow fibers 26 braided with solid fibers 28. *Id.* at p. 4, column 3, lines 35-38. In use, each of the disclosed stents are placed in the desired location within the vascular system of a patient and maintained for a period of time sufficient to allow diffusion of the surrounding fluid into the membrane and swelling of the hydrophilic material. *Id.* at p. 3, column 2, lines 48-58; p. 4, column 3, lines 57-65; and p. 4, column 4, lines 40-54. Upon inflation, the stents independently remain in place by impinging on the interior wall of the lumen. *Id.*

II. THE EXAMINER FAILED TO ESTABLISH A *PRIMA FACIE* CASE OF OBVIOUSNESS

As will become apparent from the following arguments, the rejection is improper because (1) the Examiner has failed to articulate a rationale underpinning why the Appellant's invention as a whole would have been obvious; and (2) the Examiner's proposed modification of the prior art improperly changes the principle of operation of the prior art device.

A. THE EXAMINER FAILED TO ARTICULATE A RATIONALE UNDERPINNING WHY THE APPELLANT'S INVENTION CONSIDERED AS A WHOLE WOULD HAVE BEEN OBVIOUS

The Examiner failed to establish a *prima facie* case of obviousness for claims 23 and 40, because he failed to provide a clearly articulated rationale underpinning his legal conclusion of obviousness. Section 2142 of the *M.P.E.P.* quotes the Supreme Court and the Federal Circuit with approval, reciting:

> The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, ___, 82 USPQ2d 1385, 1396 (2007) noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit. The Federal Circuit has stated that "rejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006). See also *KSR,* 550 U.S. at ___ , 82 USPQ2d at 1396 (quoting Federal Circuit statement with approval).

At p. 2100-127 through 2100-128. In other words, there must be more to the Examiner's obviousness rejection than conclusory statements. The present rejection failed to meet this requirement.

In the *Final Office Action,* in order to overcome the deficiency of *Deem et al.* to teach or make obvious the claimed reactive material being expanded when in a reacted state such that the reactive material restricts flow of blood to the vascular aneurysm when the reactive material is in the reacted state, the Examiner simply concludes that:

> [The] *Silvestrini* reference, which teaches a stent or similar structure (for example see figure 3) can be partially made of a material that is inert or solid (28) and partially made of a material that is expandable (26). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the covering (102) of [the] Deem reference of the hydrophilic material (26) of [the] Silvestrini reference to allow the reactive material to expand and to help occlude the aneurysm neck."

At p. 3, line 20 through p.4, line4. This statement merely describes the Examiner's proposed modification and concludes that the modification would be obvious to one skilled in the art. No clear rationale as to why the claimed invention would be obvious was provided.

Similarly, the Examiner also failed to provide the required articulated rationale in the *Advisory Action*. In the *Advisory Action*, the Examiner stated that:

> [T]he combination is made to show that both materials are suitable for performing the intended purpose (blocking flow of blood into the aneurysm) and therefore one of ordinary skill in the art would have recognized that more than one type of material may be used to perform the same function."

At p. 2, lines 8-10. Contrary to providing the required clearly articulated rationale, this assertion is not only nonsensical, it provides evidence that the Examiner resorted to impermissible hindsight.

For example, it is entirely unclear how combining the cited prior art *could show* that the cover 102 of *Deem et al.* and the expandable filling of *Silvestrini* are suitable for performing the intended purpose of blocking the flow of blood into an aneurysm. The cover 102 and the expandable filling are respectively taught for use in achieving entirely different goals in different manners. While *Deem et al.* is directed towards blocking the flow of blood to an aneurysm. As acknowledged by the Examiner, *Deem et al.* is silent as to employing a cover 102 comprising an expandable material.

On the other hand *Silvestrini's* stated purpose is to maintain an occluded vessel in an open configuration—not to block the flow of blood into an aneurysm. At p. 3, column 1, lines 8-11. Furthermore, there is more than a trivial gap in the logic of concluding that a disclosure teaching an expandable material taught for use as a filling for hollow fibers and serving as a support structure for a stent, as in *Silvestrini*, and a disclosure teaching a solid or nonperforated cover applied to a surface of a stent, as in *Deem et al.,* show that both materials are suitable for blocking the flow of blood into an aneurysm. The covering 102 and the expandable material are two different materials taught for use in significantly different manners for achieving vastly different objectives. In fact, *Silvestrini* teaches away from employing the expandable material to block the flow of blood. The inflated stents of *Silvestrini* are specifically configured to maintain radial openings 16 and 29 "when the stent[s] 10[, 20, 40] are in place within a body lumen." At p. 3, column 2, lines 27-31; p. 4, column 3, lines 38-41; and FIGS. 1-3.

Combining the teachings of *Deem et al.* and *Silvestrini* as proposed by the Examiner neither teaches nor makes obvious the claimed invention. Absent a resort to

impermissible hindsight based on the Appellant's disclosure, there has been simply no logical rational provided to fill the gaps in the Examiner's *prima facie* conclusion of obviousness.

Assuming for the sake of argument that a clearly articulated rationale was provided, the Examiner's conclusion of obviousness remains improper because it fails to consider the claimed invention as a whole. "In determining the difference between the prior art and the claimed invention, the question under U.S.C. 103 is not whether the differences *themselves* would have been obvious, but whether the claimed invention *as a whole* would have been obvious." *M.P.E.P.* at § 2141.02 I, p. 2100-123. Considered as a whole, the claimed apparatus or implant substantially restricts the flow of blood to the vascular aneurysm when the reactive material is in a reacted, or expanded, state. Such an apparatus or implant is simply not taught or suggested by the cited prior art. Furthermore, the Examiner has provided no evidence or logical rationale as to how the prior art makes obvious such a combination.

B. THE EXAMINER'S PROPOSED MODIFICATION OF THE PRIOR ART IMPROPERLY CHANGES THE PRINCIPLE OF OPERATION OF THE PRIOR ART DEVICE.

The Examiner failed to establish a *prima facie* case of obviousness for claims 23 and 40, because the proposed modification would change the principle of operation of the device of *Deem et al.* Section 2143.01 VI of the *M.P.E.P.* states, "[i]f the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious." At p. 2100-141; *see also id.* ("The court reversed the rejection holding the 'suggested combination of references would require a substantial reconstruction and redesign of the elements shown in [the primary reference] as will as a change in the basic principles under which the [primary reference] construction was designed to operate"). The Examiner based the presently appealed rejection on the assertion that it would have been obvious to substitute the

cover 102 of the primary reference, *Deem et al.*, with the expandable material of *Silvestrini*.

The purpose of the stent of *Deem et al.* is to obstruct flow to an aneurysm while simultaneously minimizing obstruction of flow through the healthy vessel. At p. 9, column 5, lines 18-22. The principle of operation of the stent taught by *Deem et al.* is simply to span the vascular abnormality, or aneurysm, by deployment of the stent at the site of interest and orientation of the predisposed cover 102 so as to block the vascular abnormality. At p.9, column 5, lines 45-54. In contrast to cover 102, the hydrophilic material of *Silvestrini* is confined within a membrane and expands in an aqueous environments. At p. 3, column 2, lines 26-42; p. 4, column 3, lines 29-52; and p. 4, column 4, lines 16-32.

If one were to make a material substitution, as the Examiner suggests, by making the cover 102 of *Deem et al.* out of an expandable material, a person of ordinary skill in the art at the time of the invention would recognize that it is by no means self evident or even suggested that the expandable material is structurally capable of deployment outside of a membrane, much less capable of spanning between elements 14 of the stent of *Deem et al.* *See Deem et al.* FIGS. 4 and 11B. *Silvestrini* only teaches deployment of the expandable material as a filling *within* a hollow membrane. At p. 3, column 2, lines 26-42; p. 4, column 3, lines 29-52; and p. 4, column 4, lines 16-32. At the very least, there is reason to doubt the operability of a stent incorporating the Examiner's proposed modification to perform the first intended function of *Deem et al.*, to obstruct flow to an aneurysm.

Furthermore, in view of the significant surface area of cover 102 over the stent of *Deem et al.*, as illustrated in FIG. 4, replacing a non-expandable cover material with an expandable cover material would intuitively cause a decrease in the internal diameter of the modified stent over the stent taught by *Deem et al.* Stated alternatively, a cover constructed of an expandable material would increase the thickness of the wall of the stent upon expansion. Absent a design and construction change to of the stent of

Deem et al., the Examiner's proposed modified stent would no longer function to minimize obstruction of flow through the healthy vessel because an expanded, thickened wall would effectively decrease the internal diameter of the stent of *Deem et al.* With the above point in mind, there would be no reason or motivation to make the seemingly already functioning cover 102 of *Deem et al.* out of an expandable material of *Silvestrini*.

Therefore, in addition to necessarily changing, or broadening, the principle of operation of the stent of *Deem et al.*, the Examiner's proposed modification would also require design and construction changes to compensate for the expansion, or thickening, of the stent wall. These changes in the principle of operation, design, and construction of the stent of *Deem et al.* are evidence that *Deem et al.* and *Silvestrini* are insufficient to establish the Examiner's *prima facie* case of obviousness.

III. CONCLUSION

For at least all the reasons stated herein, it is submitted that the Examiner's rejection is erroneous. As a result, the Appellant's seek a reversal of the Examiner's rejection on this appeal. Reversal is hereby affirmatively requested.

Respectfully submitted,

Dated: September 4, 2008

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CLAIMS APPENDIX

1-22. (Canceled).

23. (Previously Presented) A device for treating a vascular aneurysm comprising:

a support structure sized for placement at a region of said vascular aneurysm;

said support structure having a bridge portion spanning at least a neck region of said vascular aneurysm;

said support structure having an open, non-tubular arced configuration;

said bridge portion including a reactive material, said reactive material being expanded when in a reacted state such that said reactive material restricts flow of blood to said vascular aneurysm when said reactive material is in said reacted state.

24. (Previously Presented) A device according to claim 23, wherein said open, non-tubular arced configuration is a curved, coiled bridge configuration.

25. (Previously Presented) A device according to claim 24, wherein said arc of said non-tubular arced configuration substantially conforms to an arc of a body lumen near said vascular aneurysm.

26. (Previously Presented) A device according to claim 23, wherein said support structure includes a sinusoidal body portion.

27. (Previously Presented) A device according to claim 26, wherein said sinusoidal body portion is disposed between opposing ends of said support structure.

28. (Previously Presented) A device according to claim 23, wherein said bridge portion is comprised of said reactive material.

29. (Withdrawn) A device according to claim 23, wherein said reactive material is disposed on said bridge portion.

30. (Withdrawn) A device according to claim 23, wherein said open, non-tubular arced configuration is a vascular patch configuration.

31. (Withdrawn) A device according to claim 30, wherein vascular patch is comprised of interwoven support members.

32. (Withdrawn) A device according to claim 30, wherein said arc of said non-tubular arced configuration approximates a radius of curvature of a body lumen near said vascular aneurysm.

33. (Withdrawn) A device according to claim 30, wherein said arc of said non-tubular arced configuration is not greater than 270 degrees.

34. (Withdrawn) A device according to claim 30, wherein said support structure is malleable such that said arced configuration is adjustable.

35. (Withdrawn) A device according to claim 23, wherein said open, non-tubular arced configuration is an intra-aneurysmal neck bridge structure.

36. (Withdrawn) A device according to claim 35, wherein said intra-aneurysmal neck bridge structure comprises at least two engagement members sized to approximate a radius of curvature of said aneurysm.

37. (Withdrawn) A device according to claim 36, wherein said bridge portion is located on a region of each of said at least two engagement members.

38. (Withdrawn) A device according to claim 37, wherein said bridge portion is comprised of said reactive material.

39. (Withdrawn) A device according to claim 37, wherein said reactive material is disposed on said bridge portion.

40. (Previously Presented) An implant for treating a vascular aneurysm comprising:

an implant body sized to reside at a region of said vascular aneurysm;

said implant body having an occlusion region that substantially traverses a neck region of said vascular aneurysm;

said implant body having an arc shape, said arc shape having a sweep less than 360 degrees;

said occlusion region including a reactive material, said reactive material being expanded when in a reacted state such that said occlusion region substantially restricts flow of blood to said vascular aneurysm when said reactive material is in a reacted state.

41. (Previously Presented) An implant according to claim 40, wherein said implant body has a coiled bridge configuration.

42. (Withdrawn) An implant according to claim 40, wherein said implant body has a vascular patch configuration.

43. (Withdrawn) An implant according to claim 40, wherein said implant body has a intra-aneurysmal neck bridge configuration.

EVIDENCE APPENDIX

Exhibit 1: Final Office Action mailed February 21, 2008 ("*Final Office Action*").

Exhibit 2: Advisory Action mailed June 10, 2008 ("*Advisory Action*").

Exhibit 3: U.S. Patent Application No. 10/763,975 as filed.

Exhibit 4: U.S. Patent No. 6,231,597 to Deem et al. ("*Deem et al.*").

Exhibit 5: U.S. Patent No. 5,234,456 to Silvestrini ("*Silvestrini*").

RELATED PROCEEDINGS APPENDIX

No related proceedings are pending at this time.

EXHIBIT 1

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,975	01/22/2004	Brian J. Cox	14395-0013	7891

37374 7590 02/21/2008

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EXAMINER	
SEVERSON, RYAN J	

ART UNIT	PAPER NUMBER
3731	

MAIL DATE	DELIVERY MODE
02/21/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

EXHIBIT 1

Office Action Summary	**Application No.**	**Applicant(s)**	
	10/763,975	COX, BRIAN J.	
	Examiner	**Art Unit**	
	Ryan Severson	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-43* is/are pending in the application.

4a) Of the above claim(s) *29-39,42 and 43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23-28,40 and 41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Status

1. The status of the claims is as follows:

   a. Cancelled: 1-22

   b. Pending and Withdrawn: 29-39, 42, and 43

   c. Pending and Rejected: 23-28, 40, and 41

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. **Claims 23-28, 40, and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deem et al. (6,231,597) in view of Silvestrini (5,234,456).** Deem reference discloses a device that is a support structure (see figure 4) that is sized for placement at an aneurysm (see figure 11B). The support structure has a bridge portion or occlusion region (15, see figure 1) that spans the neck of the aneurysm (see figure 11B). The support structure has an open configuration (see figure 4). The bridge or occlusion portion includes a reactive material (102) that helps promote clotting (see column 5, lines 49-55), which restricts flow of blood into the aneurysm.

4. However, the embodiment of Deem described above does not disclose the support structure is non-tubular. Attention is drawn to figure 13 of Deem reference, which shows a support structure that does not form a complete loop (see column 8, lines 8-17) which would be beneficial because the support structure does not obstruct as much of the lumen, thereby reducing the resistance to blood flow through the area in which the support structure is placed. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the embodiment in figures 4 and 11B of Deem reference with the support structure that does not encompass the entire circumference of the lumen, as taught in figure 13 of the same reference, so as not to obstruct as much of the lumen, thereby reducing the resistance to blood flow through the area in which the support structure is placed.

5. Further regarding claim 23, Deem reference discloses substantially identical embodiments in figures 12 and 13, wherein the only difference is the fact that the end portions extend around the entire circumference of the lumen in figure 12 and do not in figure 13. This is further evidence that the support structure can perform equally well configured in either fashion and there would be no disadvantage to modifying the embodiment of figures 4 and 11B to have the end portions extend only about a portion of the circumference of the lumen.

6. Further, the reactive material of Deem reference does not expand when in a reacted state. Attention is drawn to Silvestrini reference, which teaches a stent or similar structure (for example, see figure 3) can be partially made of a material that is inert or solid (28) and partially made of a material that is expandable (26). Therefore, it

would have been obvious to one of ordinary skill in the art at the time the invention was made to make the covering (102) of Deem reference of the hydrophilic material (26) of Silvestrini reference to allow the reactive material to expand and help occlude the aneurysm neck.

7. Regarding claims 24 and 41, the arced configuration is curved and coiled (see figure 4).

8. Regarding claim 25, the configuration conforms to the lumen it is placed in (see figure 11B).

9. Regarding claim 26, the support structure includes a sinusoidal body portion (elements 14 form a sinusoidal pattern, see figure 4).

10. Regarding claim 27, the sinusoidal pattern is only disposed in the bridge portion, which lies between the opposing ends of the support structure.

11. Regarding claim 28, the bridge portion includes the reactive material (102, see figure 4).

Response to Arguments

12. Applicant's arguments with respect to claims 23 and 40 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

14. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ryan Severson whose telephone number is (571)272-3142. The examiner can normally be reached on Monday - Friday 8:30-5:00.

16. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

17. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. S./
Examiner, Art Unit 3731
/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3731

EXHIBIT 1

Notice of References Cited	Application/Control No. 10/763,975	Applicant(s)/Patent Under Reexamination COX, BRIAN J.	
	Examiner Ryan Severson	Art Unit 3731	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-5,234,456	08-1993	Silvestrini, Thomas A.	623/1.2
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

EXHIBIT 2

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,975	01/22/2004	Brian J. Cox	388700-058B	7891

37374 7590 06/10/2008
INSKEEP INTELLECTUAL PROPERTY GROUP, INC
2281 W. 190TH STREET
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TORRANCE, CA 90504

EXAMINER	
SEVERSON, RYAN J	

ART UNIT	PAPER NUMBER
3731	

MAIL DATE	DELIVERY MODE
06/10/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

RECEIVED
JUN 11 2008

EXHIBIT 2

Advisory Action Before the Filing of an Appeal Brief	Application No.	Applicant(s)	
	10/763,975	COX, BRIAN J.	
	Examiner	Art Unit	
	Ryan Severson	3731	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 21 May 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☒ They present additional claims without canceling a corresponding number of finally rejected claims.
   NOTE: *See Continuation Sheet*. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *23-28,40 and 41*.
   Claim(s) withdrawn from consideration: *29-39,42 and 43*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3731

Continuation Sheet (PTO-303) **Application No. 10/763,975**

Continuation of 3. NOTE: The addition of new claims 44 and 45 require further consideration. Further, the new claims are presented without cancelling a corresponding number of finally rejected claims.

Continuation of 11. does NOT place the application in condition for allowance because: Applicant argues that the combination proposed in the final action is improper for multiple reasons. Applicant first asserts that one of ordinary skill in the art would not look to Silvestrini for an expanding material as a replacement material for the reactive material of Deem. However, the combination is made to show that both materials are suitable for performing the intended purpose (blocking flow of blood into the aneurysm) and therefore one of ordinary skill in the art would have recognized that more than one type of material may be used to perform the same function. Applicant further discloses using the material of Silvestrini in the cover of Deem would defeat the purpose of Deem because the cover would then "likely" swell and occlude the vessel as well as the opening to the aneurysm. However, applicant provides no factual support for this assertion. Certainly the swellable material of Silvestrini does not occlude the healthy vessel, and so an argument asserting using the same material in the same way on a differently structured support structure would occlude a healthy vessel is by nature not persuasive. Finally, applicant argues Silvestrini and Deem teach away from one another because Deem is directed to restricting flow into an aneurysm and Silvestrini is directed to increasing flow in the blood vessel. Both Silvestrini and Deem maintain sufficient blood flow through the healthy blood vessel, and therefore the argument that they teach away from eachother based on two different aspects of the inventions is not persuasive. The argument could only be persuasive if one of the two references taught occluding the healthy vessel. However, since neither have this desirability, the argument is not persuasive. The rejection as set forth in the final rejection is maintained.

ANEURYSM TREATMENT DEVICE AND METHOD OF USE

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] The present application is a continuation-in-part of U.S. Patent Application Serial No. 09/909,715, entitled "Aneurysm Closure Device and Method of Use," filed on July 20, 2001, the entire contents of which are hereby incorporated by reference in its entirety. The entire contents of U.S. Patent Application No. 09/804,935, entitled "Hydrogels That Undergo Volumetric Expansion In Response To Changes In Their Environment And Their Methods Of Manufacture And Use," filed on March 31, 2001, naming Gregory M. Cruise and Michael J. Constant as co-inventors, is hereby incorporated in its entirety by this reference.

BACKGROUND

[0002] Generally, the mammalian circulatory system is comprised of a heart, which acts as a pump, and a system of blood vessels which transport the blood to various points in the body. Due to the force exerted by the flowing blood on the blood vessel the blood vessels may develop a variety of vascular disabilities or dysfunctions. One common vascular dysfunction known as an aneurysm results from the abnormal widening of the blood vessel. Typically, vascular aneurysms are formed as a result of the weakening of the wall of a blood vessel and subsequent ballooning of the vessel wall. As shown in Fig. 1, the aneurysm 10 often comprises a narrow neck portion 12 which is in communication with the blood vessel 14 and a dome portion 16 in communication with the neck portion 12. As shown in Fig. 1 the neck portion 12 and the dome portion 16 form a cavity 18. Aneurysms have been known to form in a plurality of location though the body, including, for example, the brain, the abdomen, and throughout the circulatory system.

[0003] In response, several surgical techniques for treating aneurysms have been developed. Initially, an aneurysmectomy was required to repair the dysfunctional tissue.

The aneurysmectomy procedure requires the surgeon to gain access to the aneurysm, excise the aneurysm, and replace the void with a prosthetic graft. Because this is a major surgical undertaking, the mortality rate of the procedure is relatively high. Commonly, the aneurysmectomy procedure is unavailable to patients with severe coronary or cerebral arteriosclerosis, severe restrictive pulmonary disease, and significant renal disease or other complicating factors. An alternate method of treating cerebral aneurysms called 'microsurgical clipping' requires the placement of a metallic clip across the neck of the aneurysm, thereby excluding the aneurysm from the blood flow.

[0004] In response to the shortcomings of the aneurysmectomy and the microsurgical clipping procedures, less invasive methods of treatment have been developed. Commonly, these procedures require the formation of an artificial vaso-occlusion, which is obtained by implanting a number of devices or suitable materials into the cavity 18 of the aneurysm, thereby resulting in a decrease in the flow of blood into the aneurysm. The reduced flow results in hemostasis and the formation of a clot. Generally, this procedure requires the surgeon to advance a micro-catheter to a location inside the aneurysm and deposit a biologically-compatible vaso-occlusive material or device therein. Typical vaso-occlusive devices and materials include platinum micro-coils, hog hair, microfibrillar collagen, various polymeric agents, material suspensions, and other space filling materials.

[0005] Fig. 2 shows an aneurysm 10 formed on a blood vessel 14, the aneurysm 10 having a vaso-occlusive device 20 positioned within the aneurysm dome 18. A disadvantage of filling an aneurysm with devices is that the vaso-occlusive mass may impinge on nerves or other biological structures, thereby resulting in adverse biological symptoms. For example, the impingement of the vaso-occlusive device 20 on structures or nerves within the brain, commonly known as 'mass effect', may result in adverse neurological symptoms. Another problem associated with vaso-occlusive devices is maintaining the device within the aneurysm. Blood flow through an otherwise functional blood vessel may be compromised should the device migrate from the aneurysm during or following implantation, thereby possibly resulting in a vascular embolism.

[0006] An alternate method of repairing an aneurysm has been developed which requires the implantation of a mechanical support device within the blood vessel near the neck portion of the aneurysm. Generally, these mechanical support devices, commonly referred to as "stents", comprise deployable mechanical support structures capable of delivery to a situs within the blood vessel through catheters. In addition to providing mechanical support to the dysfunctional vessel wall, the stent may include a mechanical structure which seeks to restrict the blood flow though the portion of the blood vessel proximate the aneurysm, thereby reducing or eliminating the aneurysm. Exemplary mechanical structures capable of restricting blood flow to an aneurysm include meshes or fenestrated structures which are positioned near an aneurysm 10 and restrict the flow of blood thereto.

[0007] Fig. 3 shows a stent 22 positioned in a blood vessel 14 proximal to an aneurysm 10. While a stent may provide adequate mechanical support to the blood vessel, these devices have demonstrated limited effectiveness in limiting blood flow to the aneurysm. As such, the aneurysm typically remains intact and may increase in size. In response, stents may be covered with various coatings designed to limit blood flow to the aneurysm. These coatings typically include biologically compatible polymers, films, and fabrics. However, the application of these coatings to the stents increases the cross-sectional diameter of the device, thereby resulting in a high profile stent-graft. As a result, the blood flow through the blood vessel is reduced by the presence of a high profile stent-graft. In addition, device profile is a significant problem for the treatment of cerebral aneurysms due to the small size of the cerebral blood vessels, therefore requiring the device to be deliverable to the aneurysm through a micro-catheter. As such, high profile stent-grafts are typically not used in the treatment of cerebral aneurysms.

[0008] Thus, there is presently an ongoing need for a device and method for effectively treating aneurysms without significantly affecting blood flow through the blood vessel.

SUMMARY

[0009] The aneurysm treatment devices of the present application effectively occlude or inhibits blood flow to an aneurysm without substantially impairing blood flow through the blood vessel. In addition, the aneurysm treatment devices of the present application are capable of being applied to a variety of aneurysms formed on blood vessels throughout the body.

[0010] In one embodiment, the aneurysm treatment device of the present invention comprises at least one support member and reactive material selectively applied to the support member. The at least one support member, which has at least a first surface capable of receiving the reactive material, provides a substrate for receiving the reactive material. Alternatively, the at least one support member may also provide support to weakened vascular tissue. The reactive material has a non-reacted state and a reacted state. In a reacted stated the reactive material, as selectively applied to the at least one support member, is capable of restricting or occluding the flow of blood to the aneurysm. In an alternate embodiment, the at least one support member may be manufactured from or otherwise incorporate reactive material therein. The device is preferably controllably released from an elongate delivery apparatus. The release mechanism may be any of the vaso-occlusive device and stent detachment means known in the art including but not limited to mechanical, electrolytic, electro-mechanical, thermal, hydraulic, and shape-memory means.

[0011] In an alternate embodiment, the present invention is directed to a vascular patch comprising a radially and axially flexible patch body formed by a plurality of interlocking support members. The interlocking support members, which are capable of supporting vascular tissue, form a plurality of fenestrations. A reactive material capable of restricting or occluding the flow of blood to an aneurysm is selectively applied to, woven into, integral to, or otherwise incorporated into the interlocking support member. For example, the interlocking member may be manufactured from fibrous or formed reactive material

[0012] In yet another embodiment, the present invention is directed to a coiled bridge device comprising radially and axially flexible resilient sinusoidal body member which defines a plurality of openings. The sinusoidal body member has a first radius of curvature R and a second radius of curvature R', wherein R' is larger than R. The sinusoidal body member is formed by at least one support member and has a reactive material capable of restricting or occluding the flow of blood to an aneurysm, selectively applied thereto.

[0013] In another embodiment, the present invention is directed to a helical stent having a radially and axially flexible cylindrical body member positioned between a first end and a second end. The cylindrical body member, which is formed by at least one support member capable of supporting vascular tissue, defines an internal lumen which is in communication with the first and second ends. A reactive material capable of restricting or occluding the flow of blood to an aneurysm is selectively applied to the at least one support member.

[0014] In yet another embodiment, the present invention is directed to a helical stent having a radially and axially flexible cylindrical body member positioned between a first end and a second end. The cylindrical body member, which is formed by at least one support member capable of supporting vascular tissue, defines an internal lumen which is in communication with the first and second ends. A reactive material capable of restricting or occluding the flow of blood to an aneurysm is selectively applied to the at least one support member.

[0015] In another embodiment, the present invention is directed to a reticulated expandable stent comprising radially and axially flexible cylindrical body member positioned between a first end and a second end. The cylindrical body member, which is formed by at least one support member capable of supporting vascular tissue, defines an internal lumen which is in communication with the first and second ends. A reactive material capable of restricting or occluding the flow of blood to an aneurysm is selectively applied to the at least one support member.

[0016] In still another embodiment, the present invention is directed to a bifurcated vascular support device comprising a bifurcated body member positioned between a first end, a second end, and a third end. The bifurcated body member further defines an internal lumen which communicates with the first, second, and third ends. The bifurcated body member is formed by at least one support member capable of supporting vascular tissue. A reactive material capable of restricting or occluding the flow of blood to an aneurysm is selectively applied to the at least one support member.

[0017] In another embodiment, the present invention is directed to an intra-aneurysmal bridge device comprising a flexible bridge body in communication with at least two engagement members. The at least two engagement members cooperatively form a joint. A reactive material capable of restricting or occluding the flow of blood to an aneurysm is selectively applied to the at least two engagement members.

[0018] The present invention also discloses a novel method of treating a vascular aneurysm. More particularly, the novel method of treating vascular aneurysms comprises the steps of providing a device for treating vascular aneurysms having a reactive material applied thereto, delivering the device to a vascular aneurysm, supporting the tissue near the aneurysm with the device, and allowing the reactive material to react thereby permitting the flow of blood through the blood vessel while restricting or occluding the flow of blood to the aneurysm

[0019] In yet another embodiment, the present application discloses an apparatus for treating vascular aneurysms and includes a radially expandable structure formed from at least one support member and defining a plurality of openings, and at least one reactive material selectively applied to a portion of the at least one support member. The reactive material is configured to assume a reacted state which restricts the flow of blood to an aneurysm.

[0020] In another embodiment, the present application discloses an apparatus for treating aneurysms and includes at least one support member defining an expandable

support body, at least one reactive material selectively applied to at least one support member and having a non-reacted state and a reacted state. The support member has a diameter D in a non-reacted state and a diameter D' in a reacted state, wherein diameter D' is larger than diameter D.

[0021] In another embodiment, the present application is directed to an apparatus for treating vascular aneurysms and includes an occlusive support defined by one or more support members and having a first end and a second end and a lumen formed therein, one or more fenestrations formed on the occlusive support and configured to permit blood to flow therethrough, an end cap secured to the second end and configured to restrict the flow of blood therethrough.

[0022] The present application further discloses a method of treating a vascular aneurysm and includes providing a device having a reactive material selectively applied to at least one support member, delivering the device to a position in a blood vessel proximate a vascular aneurysm, expanding the device to approximately a diameter of a blood vessel, and activating the reactive material disposed on the device to reduce the flow of blood into the aneurysm.

[0023] In another embodiment, the present application discloses a method of treating a vascular aneurysm and includes providing a device having at least one support member and an end cap secured to the support member, delivering the device to a position in a blood vessel proximate a vascular aneurysm, expanding the device to approximately the diameter of the blood vessel, and reducing a flow of blood to the aneurysm with the end cap while permitting blood flow through the blood vessel.

[0024] In another embodiment, the present application discloses a method of treating a vascular aneurysm and includes providing a device having at least one support member and an end cap secured to the support member, delivering the device to a position in a blood vessel proximate a vascular aneurysm, expanding the device to approximately the diameter of the blood vessel, delivering a catheter through the blood vessel to a position

proximate to the vascular aneurysm, inserting a space occupying material into the aneurysm, and maintaining the space occupying material within the aneurysm with the end cap to reduce the flow of blood into the aneurysm.

[0025] In another embodiment, the present application discloses a method of treating a vascular aneurysm and includes providing a device having at least one support member and an end cap secured to the support member, the end cap having a reactive material disposed thereon, delivering the device to a position in the blood vessel proximate a vascular aneurysm, expanding the device to approximately a diameter of a blood vessel, delivering a catheter through the blood vessel to a position proximate to the vascular aneurysm, inserting a space occupying material into the aneurysm, and activating the reactive material to maintain the space occupying material within the aneurysm with the end cap to reduce the flow of blood into the aneurysm.

[0026] Other objects and further features of the aneurysm treatment device of the present application will become apparent from the following detailed description when read in conjunction with the attached drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0027] The aneurysm treatment device of the present application will be explained in more detail by way of the accompanying drawings, wherein:

[0028] Fig. 1 shows a cross-sectional view of a blood vessel having a vascular aneurysm formed on its wall;

[0029] Fig. 2 shows a cross-sectional view of a prior art method of treating vascular aneurysm requiring the deposition of space-filling material within the vascular aneurysm;

[0030] Fig. 3 shows a cross-sectional view of an alternate prior art method of treating vascular aneurysm wherein a mechanical stent is positioned near an aneurysm;

[0031] Fig. 4 shows a sectional view of a support member of an aneurysm treatment device having non-reacted reactive material disposed thereon;

[0032] Fig. 5a shows a sectional view of a support member of an aneurysm treatment device having reacted reactive material disposed thereon;

[0033] Fig. 5b shows a perspective view of an embodiment of an aneurysm treatment device comprising a structure having reactive material interwoven therein in a non-reacted state;

[0034] Fig. 5c shows a perspective view of an embodiment of an aneurysm treatment device comprising a structure having reactive material interwoven therein in a reacted state;

[0035] Fig. 5d shows a perspective view of an embodiment of an aneurysm treatment device having a reactive material strand wrapped around a support member;

[0036] Fig. 5e shows a cross-sectional view of an embodiment of an aneurysm treatment device having a reactive material strand wrapped around a support member;

[0037] Fig. 5f shows a sectional view of an embodiment of an aneurysm treatment device having a support member with a variable tangential width and a reactive material strand applied thereto;

[0038] Fig. 5g shows another sectional view of an embodiment of an aneurysm treatment device having a support member with a variable tangential width and a reactive material strand applied thereto;

[0039] Fig. 6 shows a perspective view of an embodiment of an aneurysm treatment device comprising a vascular patch device useful in restricting the flow of blood to a vascular aneurysm;

[0040] Fig. 7 shows another perspective view of an embodiment of an aneurysm treatment device comprising a vascular patch device useful in restricting the flow of blood to a vascular aneurysm;

[0041] Fig. 8 shows a perspective view of an embodiment of an aneurysm treatment device positioned within a blood vessel proximate a vascular aneurysm;

[0042] Fig. 9 shows a cross-sectional view of an embodiment of an aneurysm treatment device positioned within a blood vessel proximate a vascular aneurysm;

[0043] Fig. 10 shows a perspective view of an embodiment of an aneurysm treatment device comprising a coiled bridge device useful in restricting the flow of blood to a vascular aneurysm;

[0044] Fig. 11 shows a perspective view of another embodiment of an aneurysm treatment device comprising a coiled bridge device useful in restricting the flow of blood to a vascular aneurysm;

[0045] Fig. 12 shows a cross-sectional view of an embodiment of the aneurysm treatment device of Fig. 11 positioned within a blood vessel proximate a vascular aneurysm;

[0046] Fig. 13 shows a perspective view of an embodiment of an aneurysm treatment device comprising a helical stent device useful in restricting the flow of blood to a vascular aneurysm;

[0047] Fig. 14 shows a perspective view of another embodiment of an aneurysm treatment device comprising a helical stent device useful in restricting the flow of blood to a vascular aneurysm;

[0048] Fig. 15 shows a cross-sectional view of the embodiment of the aneurysm treatment device shown in Fig. 14 positioned within a blood vessel proximate a vascular aneurysm;

[0049] Fig. 16 shows a perspective view of another embodiment of an aneurysm treatment device comprising a reticulated stent device useful in restricting the flow of blood to a vascular aneurysm;

[0050] Fig. 17 shows a perspective view of another embodiment of the reticulated stent device useful in restricting the flow of blood to a vascular aneurysm;

[0051] Fig. 18 shows a cross-sectional view of an embodiment of an aneurysm treatment device comprising a reticulated support device positioned within a blood vessel proximate a vascular aneurysm;

[0052] Fig. 19 shows a cross-sectional view of an embodiment of an aneurysm treatment device comprising a bifurcated stent device positioned within a blood vessel proximate to a vascular aneurysm;

[0053] Fig. 20 shows a sectional view of an embodiment of an aneurysm treatment device comprising an occlusive support positioned within a blood vessel proximate to a vascular aneurysm;

[0054] Fig. 21 shows a sectional view of an embodiment of an aneurysm treatment device having a catheter delivering a space occupying material to a vascular aneurysm through an occlusive support positioned within a blood;

[0055] Fig. 22 shows a perspective view of an embodiment of an aneurysm treatment device comprising an intra-aneurysmal bridge device an aneurysm treatment device useful in restricting the flow of blood to a vascular aneurysm;

[0056] Fig. 23 shows a sectional view of an embodiment of the aneurysm treatment device shown in Fig. 20 positioned within a vascular aneurysm; and

[0057] Fig. 24 shows a perspective view of an embodiment of an aneurysm treatment device positioned on an expandable balloon micro-catheter within a blood vessel.

DETAILED DESCRIPTION

[0058] Disclosed herein is a detailed description of various illustrated embodiments of the invention. This description is not to be taken in a limiting sense, but is made merely for the purpose of illustrating the general principles of the invention. The section titles and overall organization of the present detailed description are for the purpose of convenience only and are not intended to limit the present invention.

[0059] The aneurysm treatment devices of the present application are generally used to restrict the ability of blood flowing through a blood vessel from entering an aneurysm formed thereon or to otherwise limit the amount of blood within an aneyrysm. The devices disclosed herein may be applied to a blood vessel in a variety of ways, including, without limitation, conventional surgical techniques and minimally invasive surgical techniques utilizing catheters of various sizes, balloon catheters, micro-catheters, and other ways generally known in the art of minimally invasive surgery. The aneurysm treatment devices disclosed herein may be used to repair a variety of aneurysms at various locations throughout the body. For example, in one embodiment these devices may be used in procedures to repair or otherwise treat cerebrovascular aneurysms.

[0060] The devices and methods of the present application have particular compatibility with the materials and methods of manufacture and use disclosed in co-pending U.S. Patent Application Serial No. 09/804,935 filed on March 13, 2001, entitled "Hydrogels That Undergo Volumetric Expansion In Response To Changes In Their Environment And Their Methods Of Manufacture And Use," and co-pending U.S. Patent Application Serial No. 09/909,715 filed on July 20, 2001, entitled "Aneurysm Treatment Devices and Methods of

Use," each of which has been assigned to the assignee of the present application and which are incorporated by reference as if set forth herein in their entirety. Those skilled in the art will appreciate that the present invention may be manufactured with one or more of a variety of alternate reactive materials applied thereto, including, for example, collagen-polymer conjugate materials, photopolymerizable biodegradable materials, and other biodegradable cross-linked hydrogels known in the art.

[0061] Aneurysms form as a result of outward pressure applied to a diseased or damaged blood vessel wall by blood flowing within the vessel, thereby resulting in a weakened section of tissue ballooning outwardly from a blood vessel. Fig. 1 shows an aneurysm 10 comprising a neck portion 12 in communication with a blood vessel 14 and having a dome portion 16 defining aneurysm cavity 18. Those skilled in the art will appreciate Figure 1 illustrates an exemplary vascular aneurysm and is not intended to limit the scope or intent of the present invention.

[0062] One method of treating an aneurysm requires the formation of an embolism proximate to or within the aneurysm, thereby restricting or depriving the aneurysm of blood flow and reducing the likelihood the aneurysm will rupture. Figs. 2 and 3 show prior art devices used to repair aneurysms by artificially creating embolisms within or proximate to the aneurysm. In Figs. 2 and 3 the reference numerals 10, 12, 14, 16, and 18 have analogous meanings to the reference numerals identifying the features of Fig. 1. Fig. 2 shows an aneurysm 10 in communication with a blood vessel 14. As shown, a vaso-occlusive device 20 is positioned within the aneurysm cavity 18. Typically, a micro-catheter or other device is used to inject or otherwise insert the vaso-occlusive device 20 into the aneurysm cavity 18, thereby decreasing the volume of the aneurysm capable of receiving blood from the blood vessel 14. Fig. 3 shows another device useful in treating aneurysms. As shown in Fig. 3, a stent 22 is positioned within a blood vessel 14 proximate to an aneurysm 10. A stent 22 is a mechanical scaffold used to provide support to otherwise incompetent or weakened tissue or to or maintain the patency of a narrowed or occluded blood vessel.

[0063] The present application discloses various embodiments of devices useful for the embolization or isolation of aneurysms. More particularly, the present application discloses various structures capable of implantation within an aneurysm or configured to be inserted into a blood vessel proximate to an aneurysm. Exemplary aneurysm treatment devices disclosed herein include, without limitation, neck bridges, vascular patches, stents, and intra-aneurysmal implants. In one embodiment, an aneurysm treatment device may include a series of interlocking or otherwise connected support members forming a predetermined shape. In an alternate embodiment, the aneurysm treatment device comprises an implant body which may be partially or completely inserted into an aneurysm formed on a blood vessel. The implant body may form a predetermined shape or, in the alternative, may form a random shape.

[0064] Figs. 4 and 5a show cross sectional views of a portion of a support member 24 as used in the formation of a number of embodiments of the aneurysm treatment device of the present application before and following implantation. As shown in Fig. 4, the support member 24 may comprise a device substrate 26 having a reactive coating or material 28 applied to the exterior portion thereof prior to implantation. The support member 24 having a non-reacted reactive coating thereon has a first diameter of D. Fig. 5a shows reactive coating 28 disposed on the support member 24 in a reacted state, wherein the reactive coating 28 has expanded outwardly from the device substrate 26 in a preferential direction. As shown, in a reacted state the support member 24 assumes a second diameter of D', wherein the second diameter D' is larger than the first diameter D. For example, in one embodiment the second diameter D' is about 20% larger than the first diameter D. In the illustrated embodiment, the reactive coating 28 has expanded more along the horizontal axis than the vertical axis. This permits the coating to inhibit flow outwardly through the device in the radial direction while minimizing its impact on longitudinal flow through the device and also minimizing the coating's impact on the overall profile of the device.

[0065] Figs. 5b and 5c show an alternate embodiment of an aneurysm treatment device comprising a reactive material strand or wrap positioned on a support member 24. A

number of support members 24 are interwoven thereby forming an interwoven structure 27. Reactive material or strands 28 may applied to a support member 24 or positioned within the interwoven structure 27 in a radial, axial, or radially and axial orientation. For example, a support member 24 may be wrapped with a reactive material strand 28. In an alternate embodiment, a reactive strand 28 may be disposed within the interwoven structure 27. Optionally, a reactive strand 28 may be interwoven within the structure 27. Fig. 5b shows an embodiment of the aneurysm treatment device with the reactive material 28 in a non-reacted state. As shown in Fig. 5b, the orifices 29 formed by the reactive material strand 28 and surrounding support members 24 have a first area of A. Fig. 5c shows the material strands 28 of the aneurysm treatment device in a reacted state wherein the orifices 29 formed by the reactive material strand 28 and surrounding support members 24 have a second area of A'. As shown, the second area A' of the orifices 29 in a reacted state is less than the first area A of the orifices in a non-reacted state, thereby limiting the flow therethrough. For example, the second area A' of the orifices 29 in a reacted state is at least about 20% less then the first area A of the orifices in a non-reacted state.

[0066] Referring again to Figs. 4 and 5a, the support members 24 of the various embodiment of the aneurysm treatment device may be manufactured from a plurality of biologically-compatible materials. For example, in one embodiment at least one support member 24 is manufactured from materials including, without limitation, platinum, gold, tantalum, titanium, stainless steel, tungsten, Nitinol, shape memory alloys, formed reactive material, or other suitable material. Optionally, at least one support member 24 may be manufactured from a variety of biologically-compatible polymer materials, including, but not limited to, polyurethane, polyvinyl alcohol, polyester, polytetrafluoroethylene, silicone, acrylic, or similar polymeric materials. At least one support member 24 may incorporate radio-opaque or echogenic materials or agents, thereby enabling the surgeon to precisely position the device within an aneurysm, blood vessel, or other hollow organ.

[0067] At least one support member 24 used in forming an aneurysm treatment device includes at least one reactive material 28 applied thereto. The reactive material 28 may be

applied in a variety of ways known in the art. For example, one or more support members 24 may be coated with a reactive material 28. In an alternate embodiment, one or more support members 24 may have a reactive material 28 selectively applied thereto. For example, a reactive material 28 may be wrapped around or adhesively bonded to a portion of a support member 24. Figs. 5d-5e show various embodiments of an aneurysm treatment device having a reactive fiber strand 28 applied thereto. As shown, the aneurysm treatment device comprises a support member 24 defining an internal passage 25. A portion of the support member 24 includes a reactive fiber stand 28 encircling a portion of the support member 24. In one embodiment, the reactive fiber strand may be adhesively coupled to the support member 24. For example, a fiber substrate having an adhesive applied to one surface and a reactive material 28 applied thereto may be positioned on or selectively applied to one or more support members 24.

[0068] The support member 24 receiving the reactive material strand 28 may have a constant or variable diameter or tangential width. For example, Figs. 5f and 5g show an embodiment of a support member 24' having a variable tangential width. As such, the diameter of the support member 24' having the reactive material wrap 28 applied thereto is approximately equal to the diameter of surrounding support members 24. As a result, the diameter of the aneurysm treatment device in a non-reacted state remains substantially constant. In one embodiment, the reactive material wrap 28 is closely wound about the support member 24'. In an alternate embodiment, the reactive material wrap 28 may be intermittently applied to the support member 24'.

[0069] Optionally, at least one support member 24 and\or the reactive material 28 applied to the support member 24 may include one or more therapeutic agents applied thereto. Exemplary therapeutic agents include, for example, embolizing factors, anti-embolizing factors, and anti-restenotic compounds. For example, the reactive material 28 applied to one or more support members 24 may be chemically doped or impregnated with a drug, compound, and/or endothelial cell assays to promote endothelial cellular adhesion. An exemplary coating is described in US Patent Application Publication Number 2002/0049495

to Kutryk et al. which is incorporated in its entirety by this reference. In an alternate embodiment, the reactive material 28 applied to one or more support members 24 may be chemically doped or impregnated with a drug or compound to promote tissue growth or impart other therapeutic benefit about the support member 24.

[0070] The reactive material 28 may be fabricated from a plurality of materials capable of expanding or volumetrically changing over time within the presence of blood or other fluid. For example, the Applicant's co-pending U.S. Patent Application Serial No. 09/804,935 filed on March 13, 2001 entitled "Hydrogels That Undergo Volumetric Expansion In Response To Changes In Their Environment And Their Methods Of Manufacture And Use" discloses a hydrogel useful as a reactive coating or material 28 for treating aneurysms. The above-referenced hydrogel comprises 1.25g (0.021 moles) acrylamide, 0.87g (0.009 moles) sodium acrylate, 0.005g (0.00003 moles) N,N-methylenebisacrylamide, 7.95g water, and 4.5g sodium chloride (<10 micron particle size) added to an amber jar. The initiators, 53 microliters of N,N,N',N-tetramethylethylenediamine and 65 microliters of 20% w/w ammonium persulfate in water, are added and the solution is aspirated into a 3-cc syringe. The solution is then injected into 0.025" ID tubing and allowed to polymerize for 2 hours. The tubing is cut into 2-inch sections and dried in a vacuum oven. The dried hydrogel is washed 3 times in distilled water for 10-12 hours, 2 hours, and two hours, respectively, to remove porosigen, any unreacted monomer and any unincorporated monomers. The hydrogel may then be cut into sections of approximately 0.100 inch length called "pellets" and skewered with a platinum coil/wire assembly. In the alternative, the hydrogel may be drawn or formed into fibrous strands or portions of similar size and dimension as the support members 24. These pellets or strands are then hydrated in alcohol and dried under vacuum at approximately 55C for about 2 hours.

[0071] Thereafter, the dried pellets or strands are then placed in 50% hydrochloric acid/50% water and incubated for about 70 hours at 37C. After the incubation, the excess hydrochloric acid solution is rinsed off of the pellets or strands with consecutive rinses of a)

70% isopropyl alcohol: 30%water for about 5 minutes, b) 100% isopropyl alcohol for about 15 minutes, c) 100% isopropyl for about 15 minutes and d) 100% isopropyl alcohol for about 15 minutes. The hydrogel pellets or strands are then dried under vacuum at 55C for at least 2 hours. Prior to or following the complete drying process, the pellets or strands may be selectively applied to the at least one support member 24 as desired in a plurality of ways. In one embodiment the reactive material 28 is applied to the entire surface of a support member 24. For example, the reactive material 28 may be maintained in a liquid form and a support member 24 may be submerged therein, thereby coating the entire surface of the support member 24. In an alternate embodiment, the reactive material 28 is selectively applied to a portion of the support member 24. For example, the reactive material 28 may be selectively applied to the portion of a support member 24 which will engage a wall of a blood vessel. Optionally, a strand of the reactive material 28 may be wound about or around a support member 24. In another embodiment, the reactive material 28 may be applied to a substrate having a biologically compatible adhesive applied thereto. Thereafter, the substrate may be adhered to a support member 24 thereby applying the reactive material 28 thereto.

[0072] Once implanted in vivo, the reactive material 28 of the present embodiment becomes fully swollen after approximately one hour at physiological pH (about 7.4). For example, in one embodiment the reactive material 28 positioned on the support member 24 from a diameter of about 0.026 inch to a diameter of about 0.035 inch. As such, the cross sectional diameter of the support member 24 having reacted reactive material 28 thereon is about 25% larger than the cross sectional diameter of the support member 24 having non-reacted reactive material 28 thereon. Alternatively, the strands of reactive material 28 may be woven or integrated into the support structure. Optionally, the support structure 24 may be manufactured from a reactive material 28 without a substrate 26. (See Fig. 4)

[0073] Figs. 6-9 show an embodiment of an aneurysm treatment device useful in isolating an aneurysm from a blood vessel. As shown in Fig. 6, the aneurysm treatment device comprises a vascular patch device 30 having a body member 32 formed by a

plurality of interwoven or otherwise joined support members 24 axially displaced in relation to each other and capable of supporting weakened vascular tissue. The interwoven support members 24 form a plurality of fenestrations 34. In Figs. 6-8, a reactive material 35 is selectively applied to the interwoven support members 24. As illustrated, the present embodiment permits the isolation and embolization of an aneurysm formed on a blood vessel without substantially occluding blood flow therethrough. As shown in Fig. 7, the vascular patch device 30 is formed by the plurality of support members 24 and may have an arcuate profile 36. In one embodiment, the arcuate profile 36 may be selected to approximate the radius of curvature of the receiving blood vessel, thereby further limiting blood vessel occlusion following implantation. The vascular patch device 30 may be manufactured in a variety of sizes, lengths, and radiuses. For example, the vascular patch device 30 may approximate 270 degrees of the receiving blood vessel, thereby using mechanical force to secure the device within the blood vessel. If desired, the vascular patch device 30 may incorporate malleable support members 24, thereby permitting the surgeon to adjust the arcuate profile 36 to conform to the radius of curvature of the receiving blood vessel during implantation.

[0074] Referring to Fig. 8, a vascular patch device 30 is shown positioned within a blood vessel 14 proximate to an aneurysm 10, wherein the device 30 traverses the opening 38 to the aneurysm cavity 18 formed by the neck portion 12. As shown, the expansion of the reactive coating 35 results in a decrease in the size of the fenestrations 34 formed in the vascular patch device 30, thereby reducing the amount of blood entering the aneurysm. In an alternate embodiment, the device 30 may include a plurality of attachment devices (not shown) to assist in implanting and securing the device within a blood vessel. The attachment devices may include, for example, hooks, barbs, or similar devices manufactured from a plurality of materials, such as platinum, gold, tantalum, titanium, stainless steel, Nitinol, or other suitable material. In an alternate embodiment, the vascular patch device 30 may incorporate alternate attachment mechanisms, including, without limitation, adhesive materials, mechanical attachment mechanisms, or vacuum attachment mechanisms. Fig. 9 shows a cross sectional view of a blood vessel 14 having the vascular

patch device 30 positioned proximate to an aneurysm 10. Those skilled in the will appreciate the present embodiment may be manufactured in a plurality of sizes, thereby enabling usage in various blood vessels to repair a plurality of aneurysms.

[0075] Figs. 10-12 show an alternate embodiment of an aneurysm treatment device useful in treating aneurysms. As shown in Fig. 10, the aneurysm treatment device includes a resilient coiled bridge device 40 having a sinusoidal body member 42 defining a plurality of openings 44. The body member 42 may be formed along an arc 46, thereby aiding in the implantation of the device while limiting the occlusion of blood vessel. The resilient body member 42 may be compressed along the line 48 to enable delivery and positioning of the coiled bridge device 40 in vivo. Upon placement of the coiled bridge device 40 the resiliency of body member 42 exerts an outward pressure along line 50, wherein the resilient body member 42 engages the blood vessel wall (not shown). In an alternate embodiment, the coiled bridge device 40 may be used to provide mechanical support to weakened vascular tissue. As shown in Fig. 10, the body member 42 is coated with or otherwise disposes a reactive coating, thereby occluding or otherwise inhibiting the flow of blood to the aneurysm. Fig. 11 shows an alternate embodiment of the coiled bridge device 40 comprising a resilient sinusoidal body member 42 having at least one reactive section 52 disposed thereon, and defining a plurality of openings 44. The reactive portions 52 are areas selectively coated or otherwise incorporating a reactive material as defined above. The present embodiment permits the embolization of the aneurysm while limiting the occlusion within the blood vessel. Fig. 12 shows a cross sectional view of an aneurysm treatment device positioned within a blood vessel 14 wherein the at least one reactive section 52 occludes or inhibits blood flow to an aneurysm 10.

[0076] Figs. 13-15 show yet another embodiment of an aneurysm treatment device useful in treating aneurysms formed on weakened vascular tissue. Figs. 13-15 show various implantable expandable intraluminal prosthetic devices commonly referred to as "stents" capable of embolizing or isolating an aneurysm formed on weakened blood vessel tissue. In an alternate embodiment, the intraluminal vascular prosthetic devices may be

used to provide mechanical support to weakened vascular tissue. As shown in Fig. 13, a helical expandable stent 54 comprises a cylindrical body member 60 disposed between a first end 56 and a second end 58. The cylindrical body member 60 defines a central lumen 62 co-axially aligned with the longitudinal axis 64 of the stent 54. The helical expandable stent 54 has a first diameter, D, thereby enabling insertion and positioning of the device within a blood vessel, and a larger second diameter, D', which is capable of engaging and supporting a blood vessel wall. As shown, a reactive material 66 is selectively applied to the external surface of the helical expandable stent 54. Fig. 14 shows an alternate embodiment of the helical expandable stent 54, comprising a cylindrical body member 60 having a first end 56 and a second end 58. The cylindrical body member 60 further comprises at least one reactive section 66 disposed thereon, thereby enabling the embolization or isolation of an aneurysm while limiting blood vessel occlusion. Fig. 15 shows cross sectional view of the present embodiment positioned within a blood vessel 14, wherein the at least one reactive section 66 occludes or otherwise inhibits blood flow to an aneurysm 10.

[0077] In another embodiment, Figs. 16-18 show various embodiments of reticulated expandable intraluminal stents. As shown in Figs. 16 and 17, the reticulated stent 68 comprises a first end 70 and a second end 72, having a cylindrical reticulated body 74 positioned therebewteen. The cylindrical reticulated body 74, which is comprised of a series of interconnected support members 24, defines a flow lumen 76 co-axially aligned along the longitudinal axis 78 of the stent 68 having a first compacted diameter D, and a second larger diameter D'. As shown in Figs. 16-18, a reactive material may be applied to the external portion of the stent 68. Alternatively, the reactive material may be applied to selected areas or individual support members 24 may be manufactured from reactive material or otherwise incorporated therein. Fig. 18 shows an embodiment of the reticulated expandable stent 68 positioned within a blood vessel 14, wherein a reactive section 80 is occluding or otherwise inhibiting the flow of blood to an aneurysm 10.

[0078] Fig. 19 show an embodiment of an occlusive bifurcated supports. As shown in Fig. 19, the occlusive bifurcated support 82 comprising a first end 84, a second end 86, and a third end 88 and having a cylindrical body 90 positioned between the first, second, and third ends, 84, 86, and 88, respectively. The cylindrical body 90 further defines an internal lumen 92, which is in communication with the first, second, and third ends, 84, 86, and 88, respectively. The occlusive bifurcated support 82 has first diameter D, thereby enabling insertion and positioning of the device within a blood vessel, and a larger second diameter D', which is capable of engaging a blood vessel wall. As such, the cylindrical body 90 may be manufactured from a plurality of interlocking or otherwise joined support members 24, and may be reticulated. Reactive material 92 is incorporated into the cylindrical body 82, thereby occluding the aneurysm 10 formed on the blood vessel 14.

[0079] Figs. 20 and 21 show an embodiment of an occlusive support device. As shown in Fig. 20, an aneurysm 110 may form on a blood vessel 114 at a vascular junction. The blood vessel 114 includes a first passage 116, a second passage 118, and a third passage 120. The occlusive support device 100 comprises one or more support members 122 forming a first end 124 and a second end 126 and defining a lumen 128 therethrough. One or more fenestrations 130 may be defined by the one or more support members 122. When implanted the one or more support member 122 provide support along line L to the surrounding tissue while permitting blood to flow through the fenestrations 130 formed by the support members 122. An end cap may be secured to the second end 126 of the occlusive support device 100. In one embodiment the end cap 132 is comprised of a support member 122 having reactive material 133 applied thereto. For example, as shown in Figs. 20 and 21 the end cap 132 comprises a support member 122 formed in a circular shape of decreasing diameter. In an alternate embodiment, the end cap 132 may be comprised of a plurality of interwoven support members 122 thereby forming a fenestrated end cap. The end cap 132 may be comprised from one or more filamentary elements that can easily be linearized for movement through a catheter. Optionally, the end cap 132 is comprised of reactive material 133. As such, the end cap 132 may have no reactive material thereon, reactive material 133 applied thereto, or manufactured solely from one or

more reactive materials 133. Once implanted, the end cap 132 decreases the flow of blood from the first passage 116 of the blood vessel into aneurysm 110 formed at the vascular junction, thereby directing the blood flow into the second and third passages 118, 120. As shown in Fig. 21, a space-occupying material 136 may be injected into the aneurysmal space 138 formed in the aneurysm 110. For example, a catheter 134 may be advanced though occlusive device 100 positioned within a blood vessel 114 and inserted through the end cap 132 into the aneurysmal space 138. Thereafter, a space occupying material 136 may be injecting or inserted into the aneurysmal space 138 from the catheter 134. Exemplary space occupying material 136 include, without limitation, hydrogels, hog hair, microfibrillar collagen, various polymeric agents, material suspensions, metallic or radio-opaque materials, and other space filling materials. In an alternate embodiment, therapeutic agents may be delivered to the aneurysmal space 138 through the catheter 134. Once the space occupying material 136 has been inserted into the aneurysmal space 138 the end cap 132 may be used to maintain the space occupying material 136 within the aneurysm 110 or to facilitate the formation of a substantially continuous surfacce bridging the neck of the aneurysm 110.

[0080] Figs. 22 and 23 show an embodiment of an intra-aneurysmal neck bridge structure. As shown, the intra-aneurysmal neck bridge structure 150 comprises device body 152 in communication with at least two engagement members 154A and 154B cooperatively forming a device joint 156. In one embodiment, the device joint 156 sealably isolates the aneurysm from the flow of blood through the blood vessel. The engagement members 154A-B are formed to approximate the radius of curvature of the aneurysm thereby providing an interface between the device and the aneurysm. Reactive portions 158A-B are positioned on the engagement members 154A-B, respectively. As shown in Fig. 23, a reactive or occlusive material 160 may be inserted into the aneurysm 162 prior to or after applying the intra-aneurysmal neck bridge structure 150. Such reactive or occlusive materials 160 may include, for example, a plurality of materials such as hydrogels, hog hair, microfibrillar collagen, various polymeric agents, material suspensions, metallic or radio-opaque materials, and other space filling materials.

[0081] The present application further discloses methods of treating vascular aneurysms. In the one embodiment, a method of percutaneously inserting an aneurysmal treatment device into an aneurysm is disclosed and includes percutaneously inserting am aneurysmal treatment device into a blood vessel, advancing the treatment device to a location proximate to a vascular aneurysm, and applying the device to the aneurysm or surrounding tissue without substantially restricting blood flow through the blood vessel. The aneurysm treatment devices disclosed in the present application may be delivered to a situs in vivo in a plurality of manners, including, for example, on guidewires, balloon catheters or through micro-catheters. Fig. 24 shows an exemplary embodiment 170 of an aneurysm treatment device being applied to an aneurysm 172 using a balloon micro-catheter 174.

[0082] In practice, the surgeon positions an aneurysm treatment device, for example, an expandable reticulated stent 170 on a delivery device, for example, a micro-balloon catheter 174. Thereafter, a first incision is made proximate a blood vessel and a guidewire 176 is inserted therein. Commonly, the guidewire will enter the circulatory system through the femoral artery, the femoral vein, the jugular vein, the carotid artery, or a similar blood vessel. The guidewire 176 may then be directed through the circulatory system to a location proximate to the aneurysm 172 and, thereafter, made to exit the body through a remote exit point. The delivery device 174 and stent 170 may then be advanced along the guidewire 176 and positioned proximate to the aneurysm 172. Typically, visualization methods, such as fluoroscopy, ultrasound visualization, or echogenic location are utilized to precisely position the delivery device near or within the aneurysm 172. Once positioned, the micro-balloon 174 is inflated and the expandable reticulated stent 170 is applied to the tissue. The portion of the expandable reticulated stent 170 disposing the reactive material 178 is positioned proximate to the aneurysm. Thereafter, the delivery device 174 and guidewire 176 are removed from the body. The activation of the reactive material 178 selectively applied to the stent 170 restricts or occludes the flow of blood to the aneurysm 172. The activation process may result from a plurality of occurrences, including, for example, the presence of a physiological pH for an extended period, the presence of an

enzyme or other material within the blood, electromagnetic-activation resulting from the introduction of a pre-determined wavelength of electromagnetic energy. The procedure above discloses one such activation method, however, other activation methods known in the art are contemplated.

[0083] In closing it is understood that the embodiments of the aneurysm treatment device disclosed herein are illustrative of the principles of the invention. Other modifications may be employed which are within the scope of the invention. Accordingly, the present invention is not limited to that precisely as shown and described in the present invention.

What is claimed is:

1. An apparatus for treating vascular aneurysms, comprising:

a radially expandable substantially cylindrical structure formed from a plurality of support members and defining a plurality of openings; and

at least one reactive material strand selectively integrated into the substantially cylindrical structure, the reactive material strand having a non-reacted state and a reacted state, wherein the reactive material strand in the reacted state is configured to restrict a flow of blood to an aneurysm.

2. The apparatus of claim 1, wherein the reactive material strand is an expandable polymer.

3. The apparatus of claim 1, wherein the reactive material strand is a hydrogel.

4. The apparatus of claim 1, wherein the reactive material strand is responsive to pH.

5. The apparatus of claim 1 wherein the reactive material strand applied to the support members defines the plurality of openings, wherein each opening has an area A when the reactive material strand is in a non-reacted state and has an area A' when the reactive material strand is in a reacted state, and wherein area A' is less than area A.

6. The apparatus of claim 5, wherein the area A' is at least about 20% less than the area A.

7. The apparatus of claim 1, wherein the reactive material strand is interwoven into the substantially cylindrical structure.

8. The apparatus of claim 1, wherein the reactive material strand is selectively positioned on one or more of the support members.

9. The apparatus of claim 8, wherein the reactive material strand is positioned on one or more of the support members in a radial orientation.

10. The apparatus of claim 8, wherein the reactive material strand is positioned on one or more of the support members in an axial orientation.

11. The apparatus of claim 8, wherein the reactive material strand is positioned on one or more of the support members in a radial and axial orientation.

12. The apparatus of claim 8, wherein the reactive material strand is wrapped around one or more of the support members.

13. The apparatus of claim 8, wherein the reactive material strand is adhesively bonded to one or more of the support members.

14. The apparatus of claim 8, wherein the reactive material strand has a variable diameter.

15. The apparatus of claim 8, wherein the reactive material strand has a variable tangential width.

16. The apparatus of claim 8, wherein the reactive material strand is intermittently applied to one or more of the support members.

17. The apparatus of claim 1, wherein each support member has a diameter D when the reactive material strand is in a non-reacted state and a diameter D' when the reactive material strand is in a reacted state, and wherein diameter D' is larger than diameter D.

18. The apparatus of claim 1 further comprising at least one therapeutic agent applied to at least one of the support members and the reactive material strand.

19. The apparatus of claim 18 wherein the therpeutic agent is selected from the group consisting of embolizing factors, anti-embolizing factors, anti-restenotic compounds, endothelial cell assays, compounds to promote endothelial cellular adhesion, and growth factors.

20. An apparatus for treating vascular aneurysms, comprising:

a radially expandable structure formed from a plurality of support members interwoven to form an interwoven structure and defining a plurality of openings; and

at least one reactive material strand interwoven into the interwoven structure, the reactive material strand having a non-reacted state and a reacted state, wherein the reactive material strand in the reacted state is configured to restrict a flow of blood to an aneurysm.

21. An apparatus for treating vascular aneurysms, comprising:

a radially expandable structure formed from a plurality of support members interwoven to form an interwoven structure and defining a plurality of openings; and

at least one reactive material strand wrapped around one or more support members, the reactive material strand having a non-reacted state and a reacted state, wherein the reactive material strand in the reacted state is configured to restrict a flow of blood to an aneurysm.

22. An apparatus for treating vascular aneurysms, comprising:

a radially expandable substantially cylindrical structure formed from a plurality of support members and defining a plurality of openings; and

at least one reactive material strand selectively interwoven into the substantially cylindrical structure, the reactive material having a non-reacted state and a reacted state,

wherein the reactive material strand in the reacted state is configured to restrict a flow of blood to an aneurysm.

ANEURYSM TREATMENT DEVICE AND METHOD OF USE

ABSTRACT

The present application discloses an apparatus for treating vascular aneurysms and includes a radially expandable substantially cylindrical structure formed from a plurality of support members and defining a plurality of openings, and at least one reactive material strand selectively integrated into the substantially cylindrical structure. The reactive material is configured to assume a non-reacted state and a reacted state. The reactive material in the reacted state is configured to restrict a flow of blood to an aneurysm.

EXHIBIT 3

FIG. 1

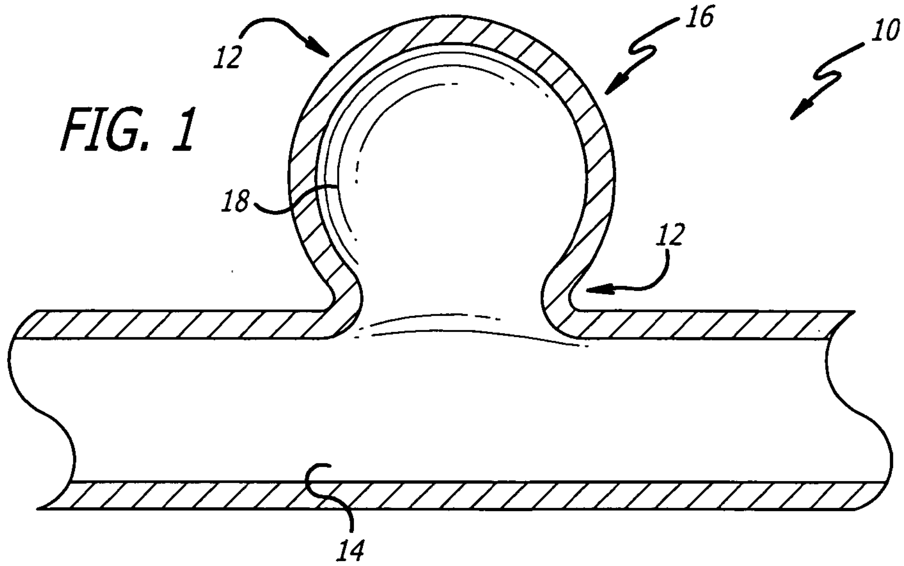


FIG. 2

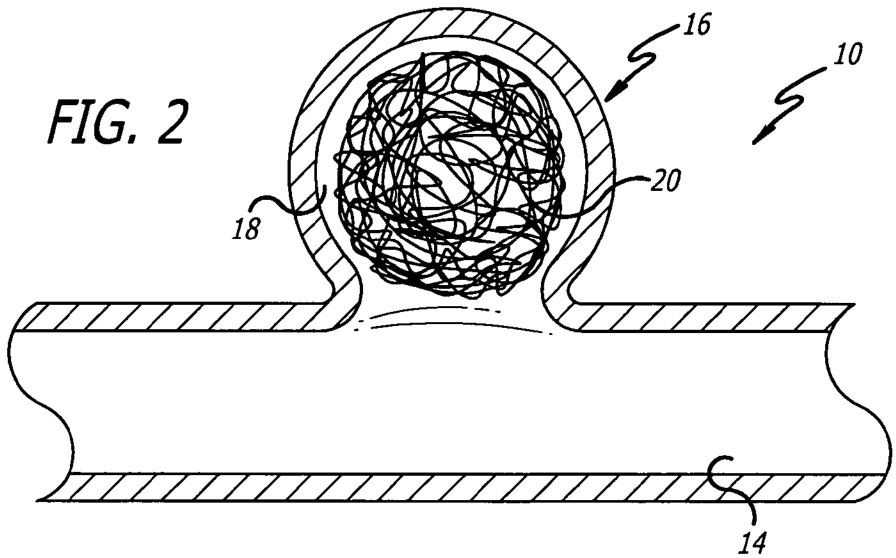


FIG. 3

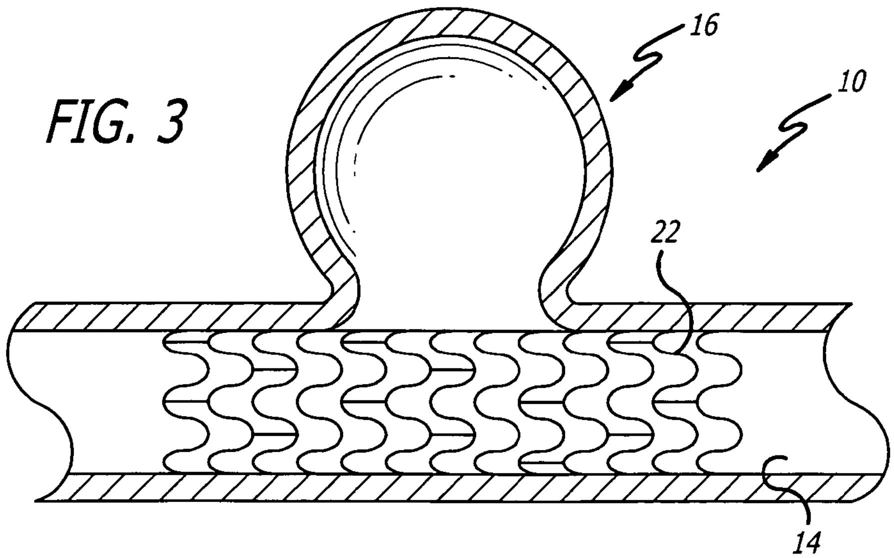


EXHIBIT 3

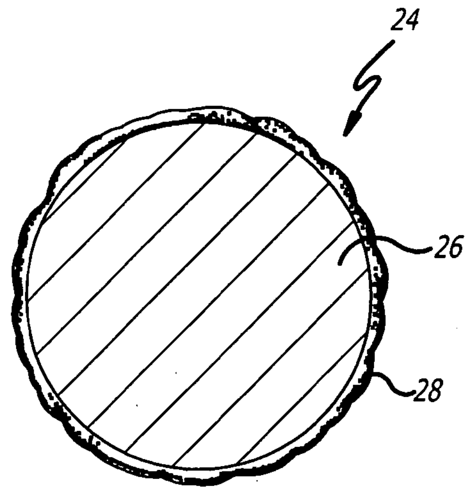
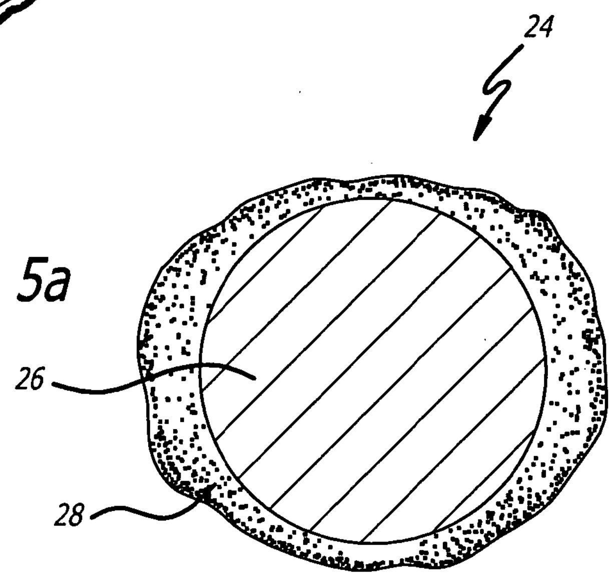


FIG. 4

FIG. 5a



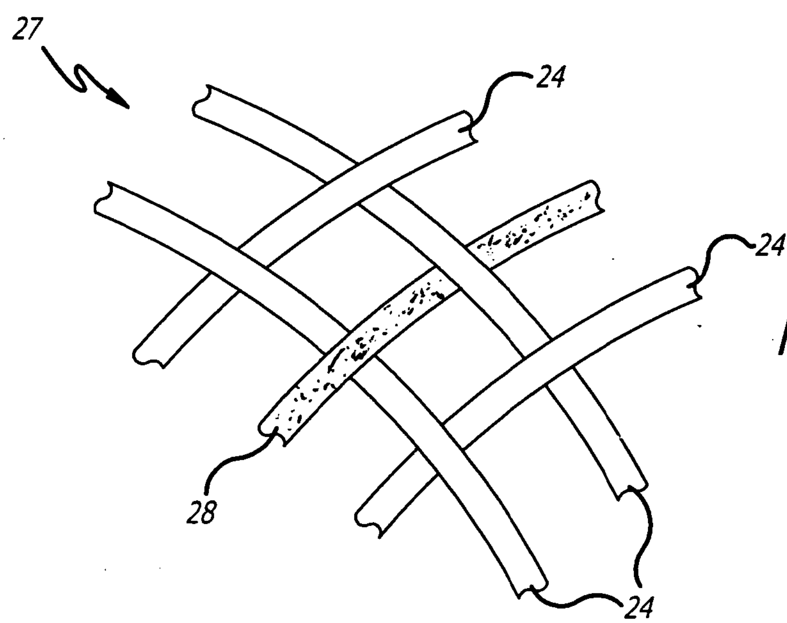
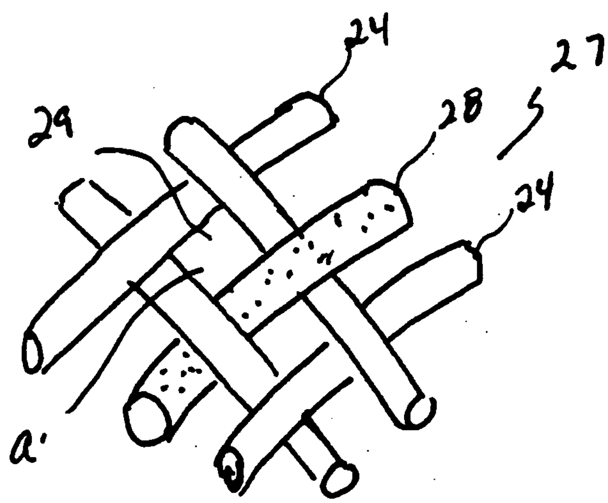


FIG. 5b

Fig. 5c



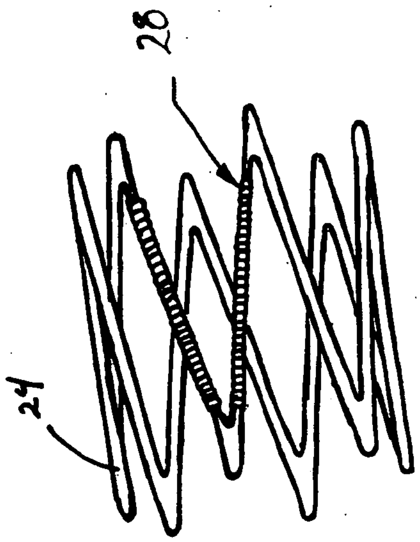


Fig. 5D

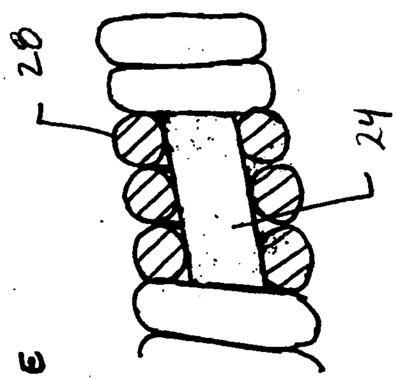


Fig. 5E

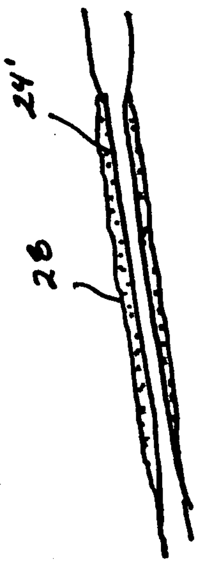


Fig. 5F

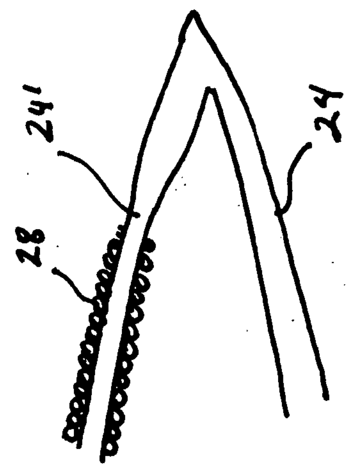


Fig. 5G

EXHIBIT 3

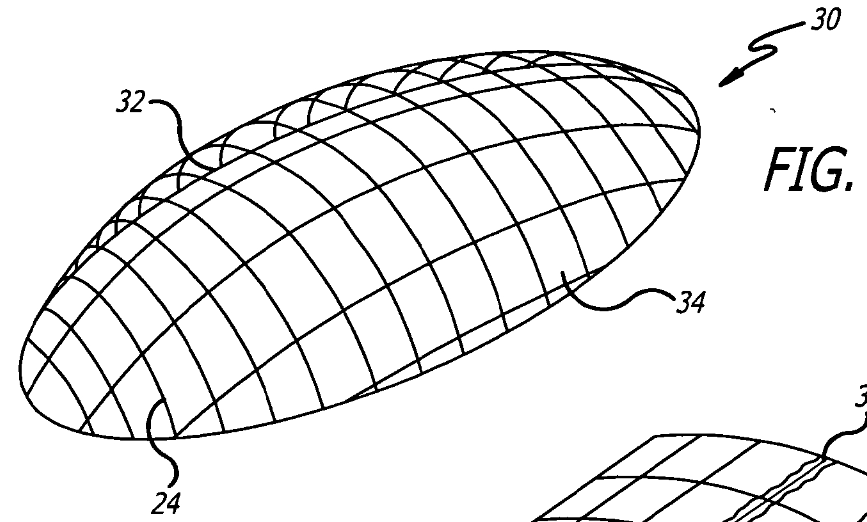


FIG. 6

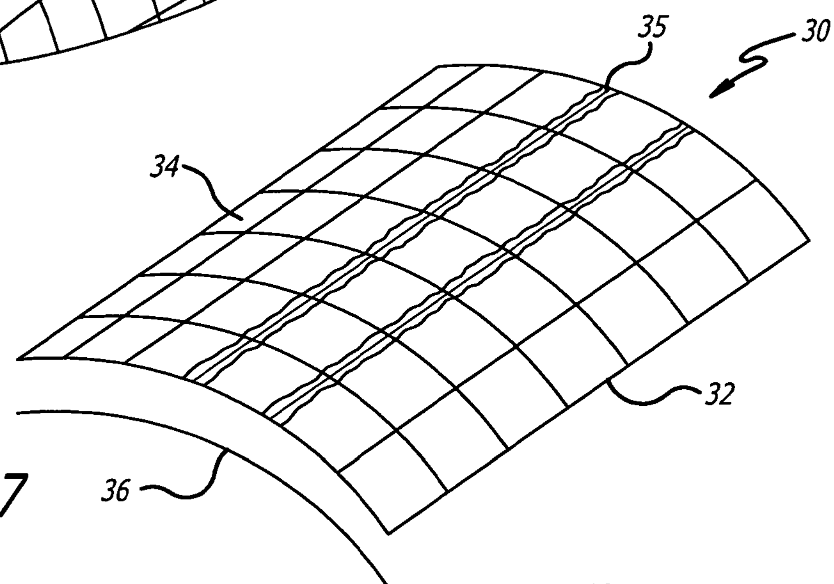


FIG. 7

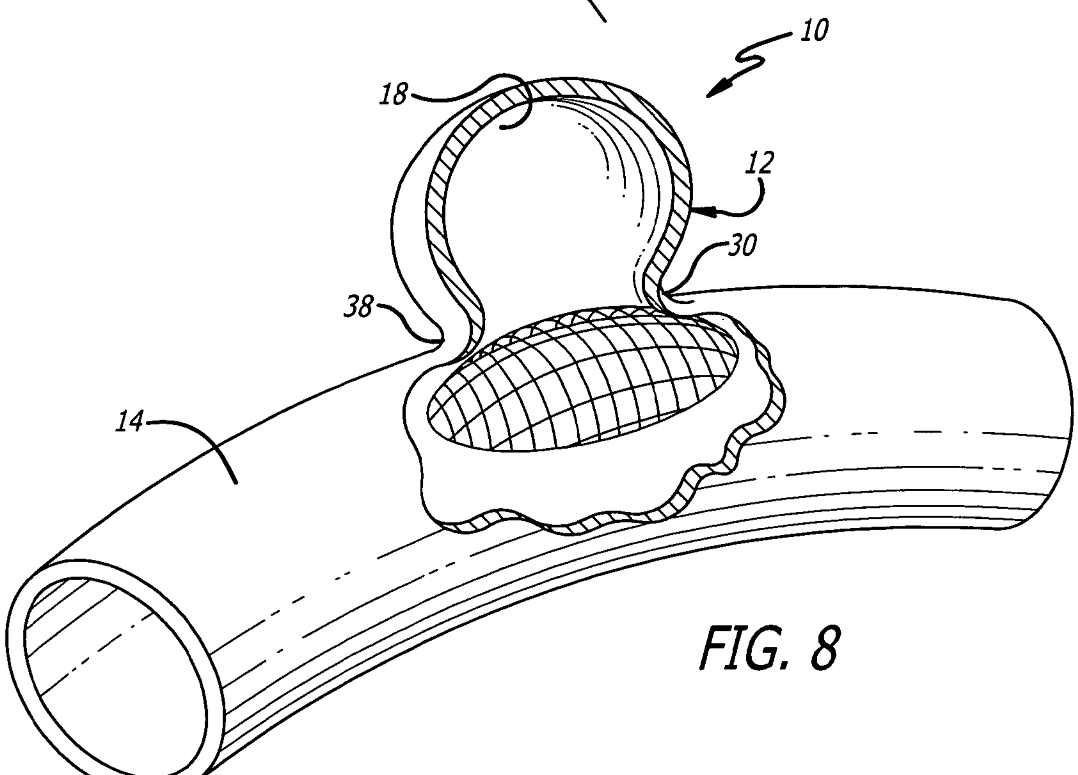


FIG. 8

EXHIBIT 3

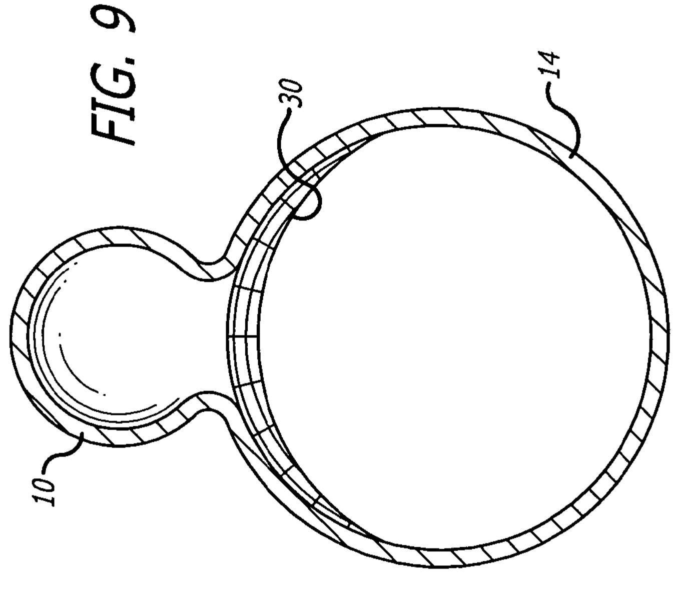


FIG. 9

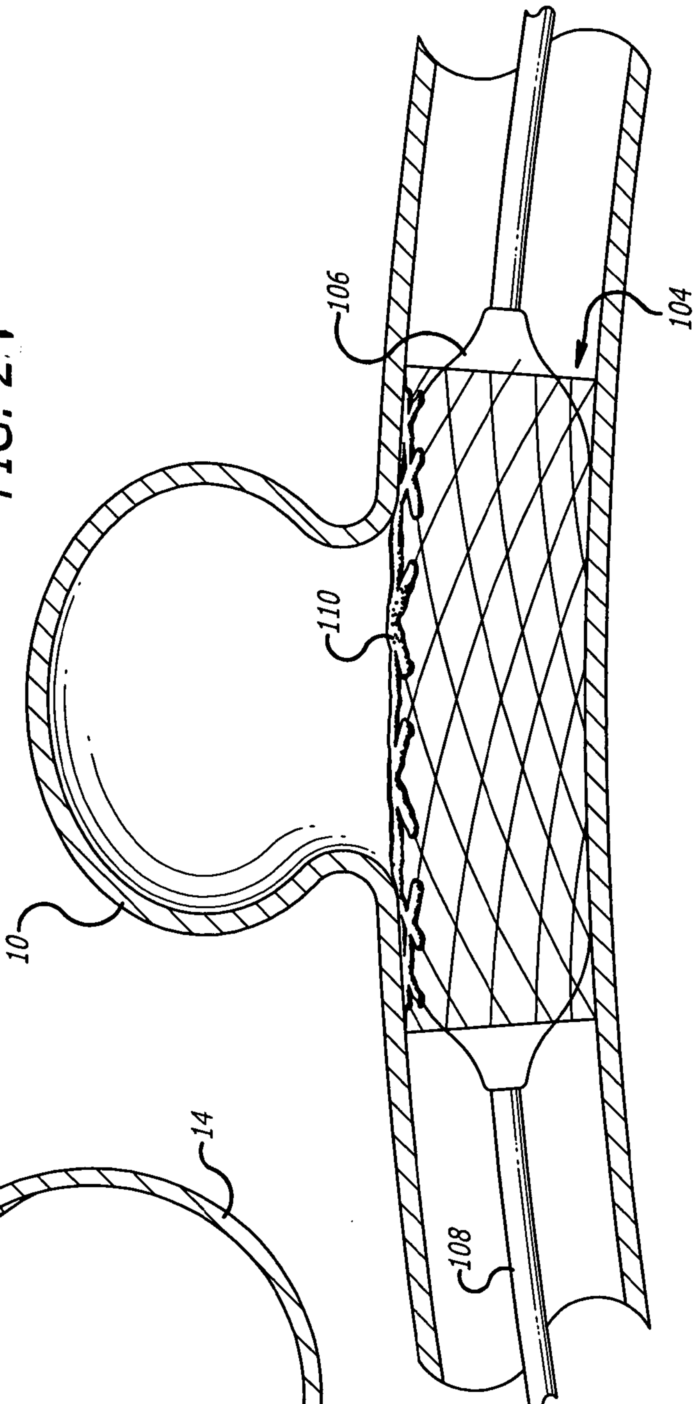
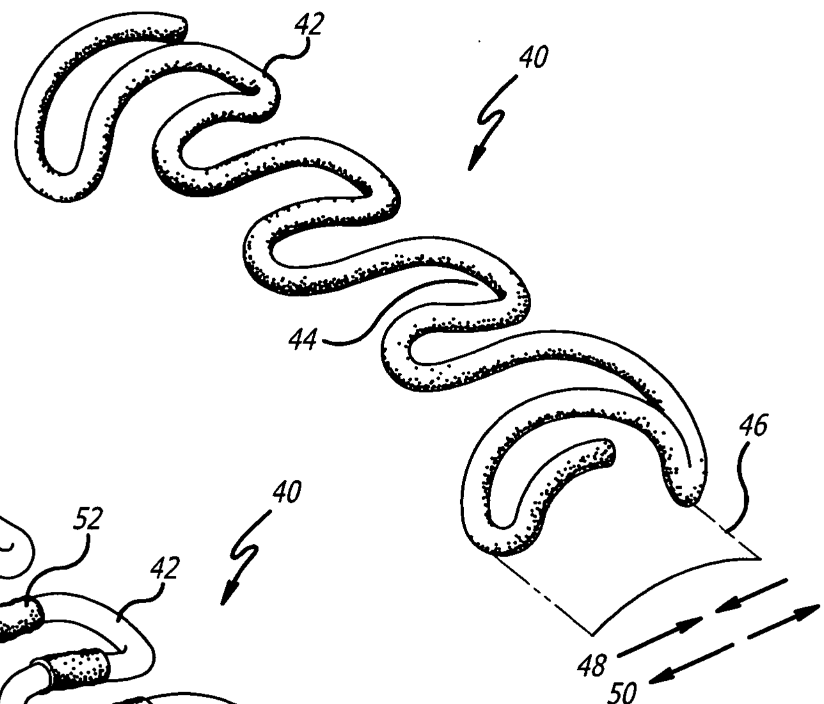


FIG. 24

FIG. 10



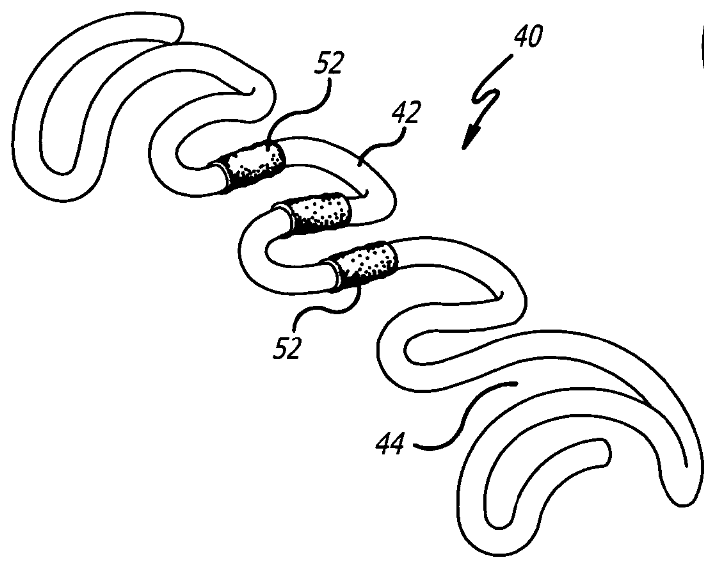


FIG. 11

FIG. 12

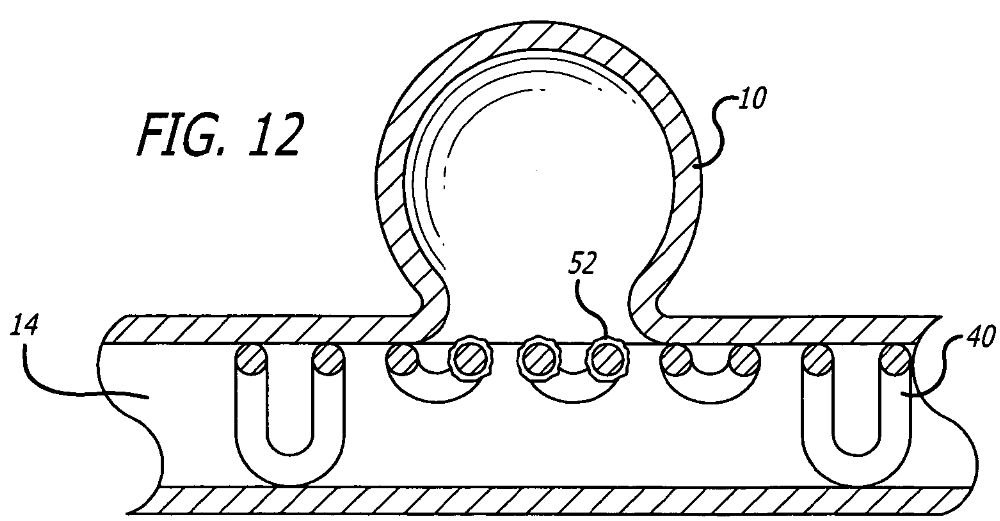
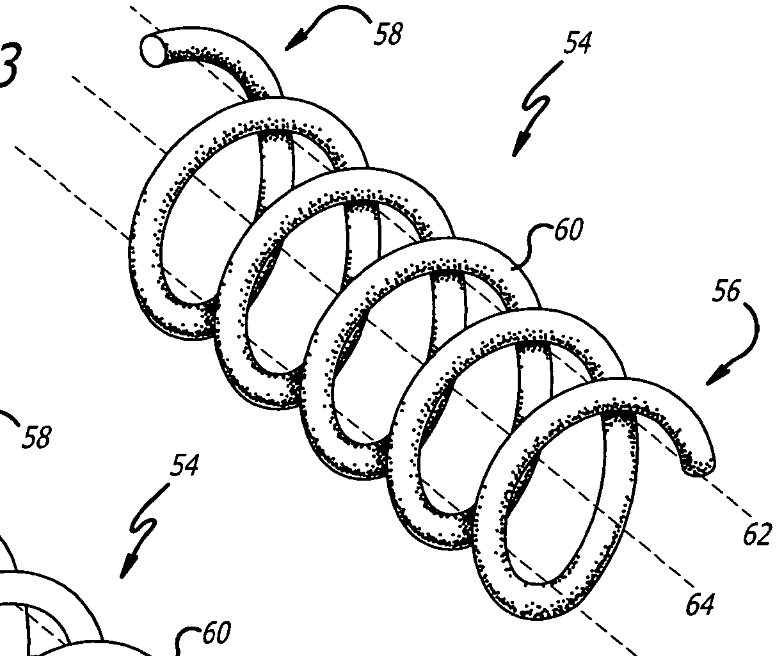


EXHIBIT 3

FIG. 13



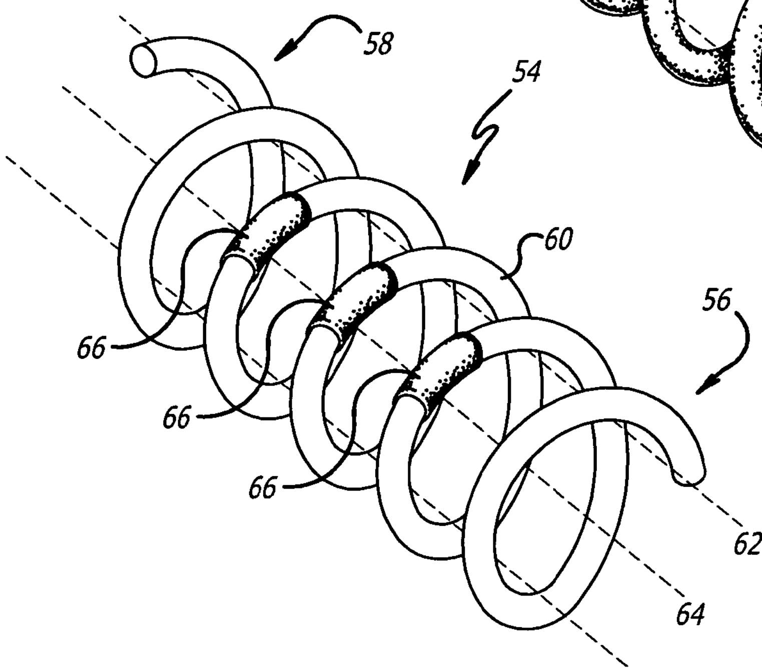
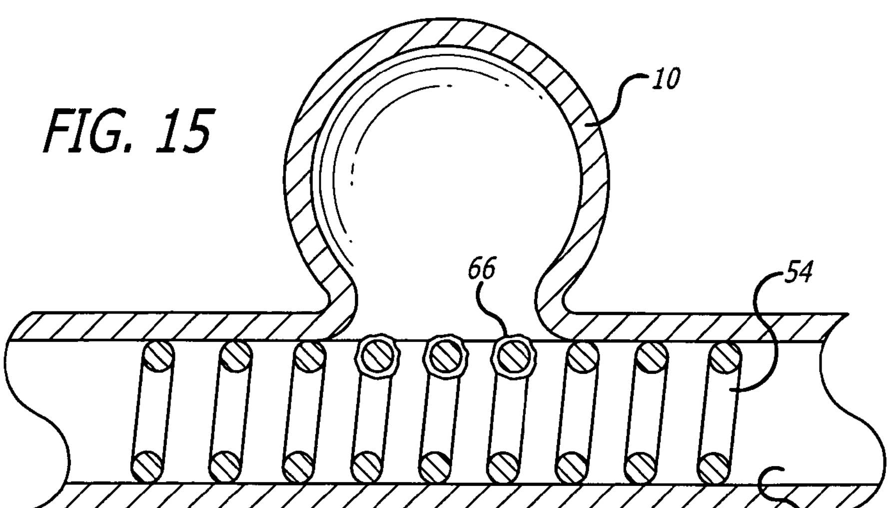


FIG. 14

FIG. 15



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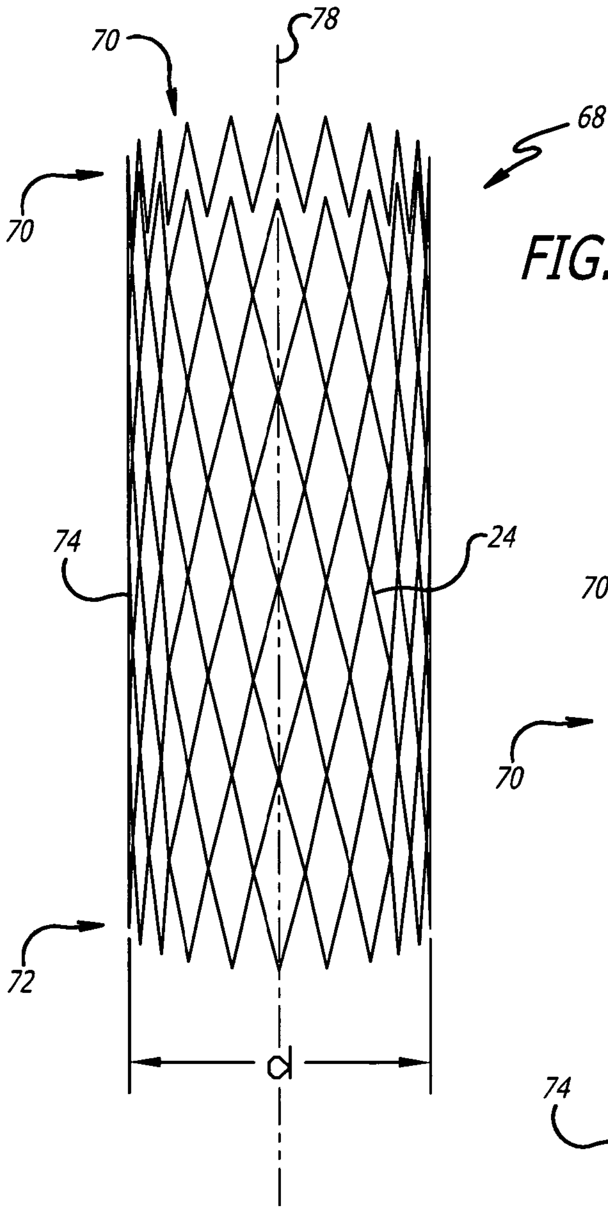


FIG. 16

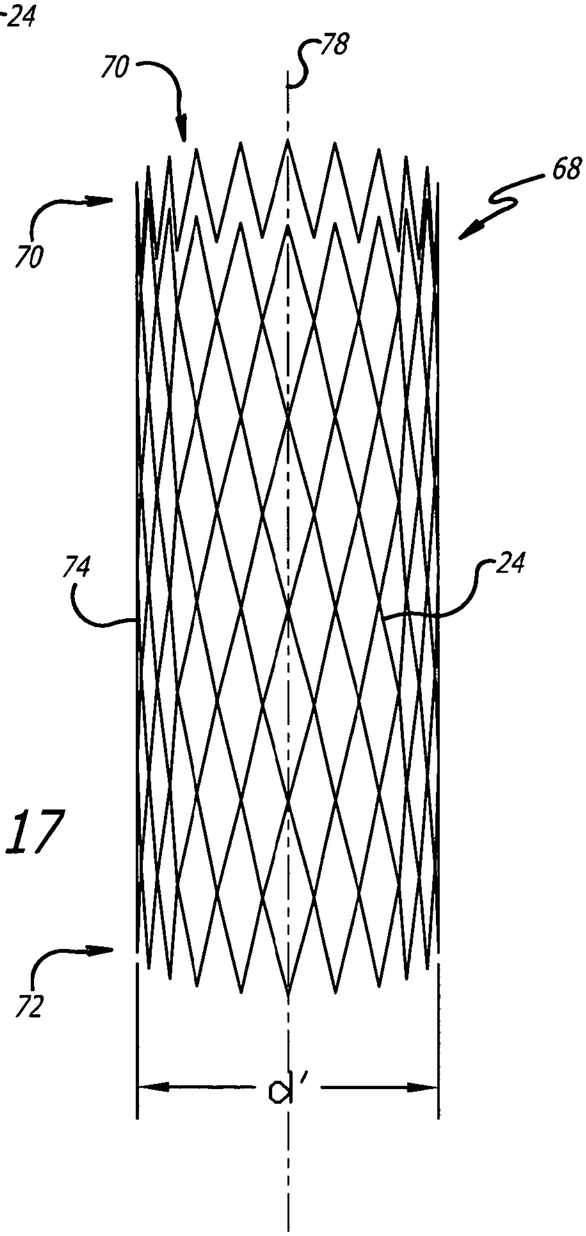


FIG. 17

EXHIBIT 3

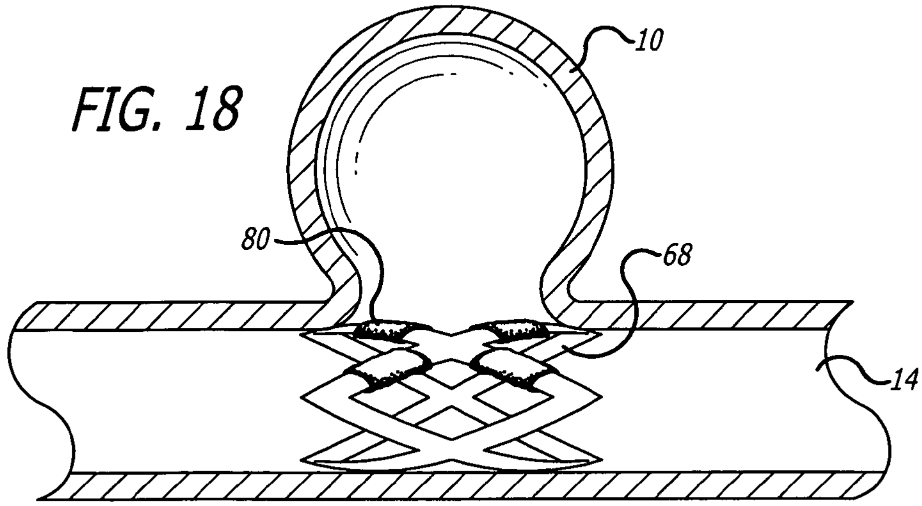


FIG. 18

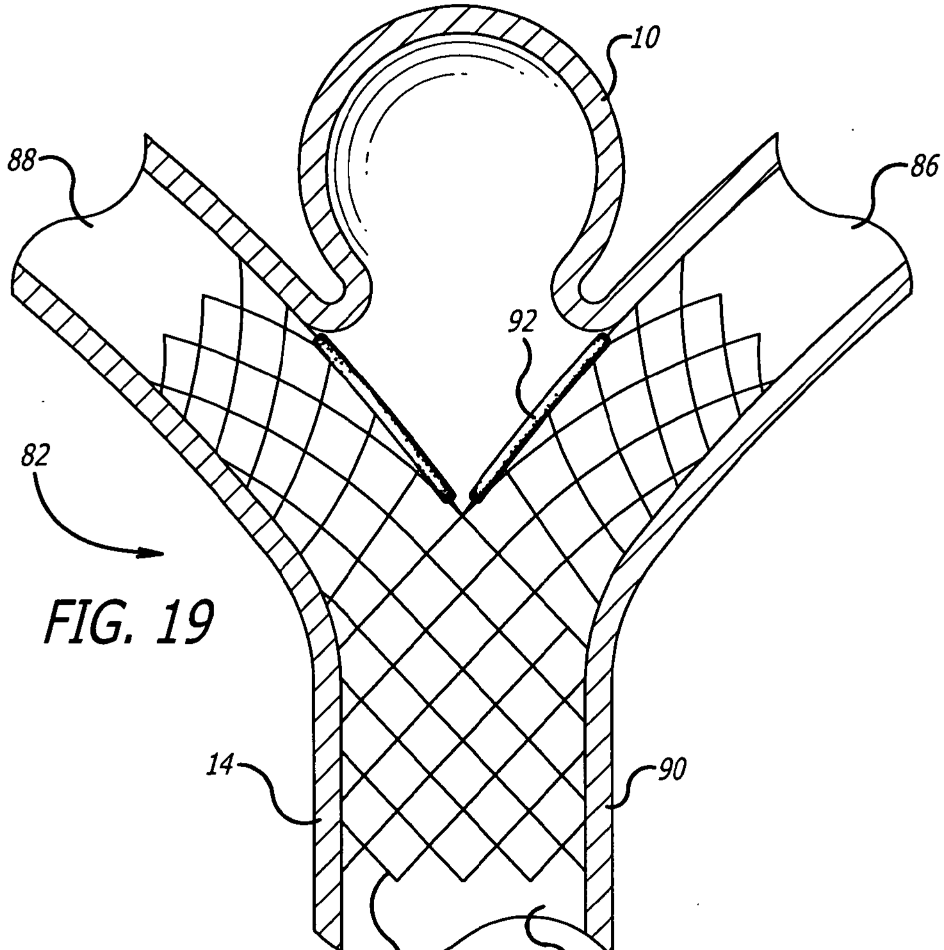


FIG. 19

Fig. 20

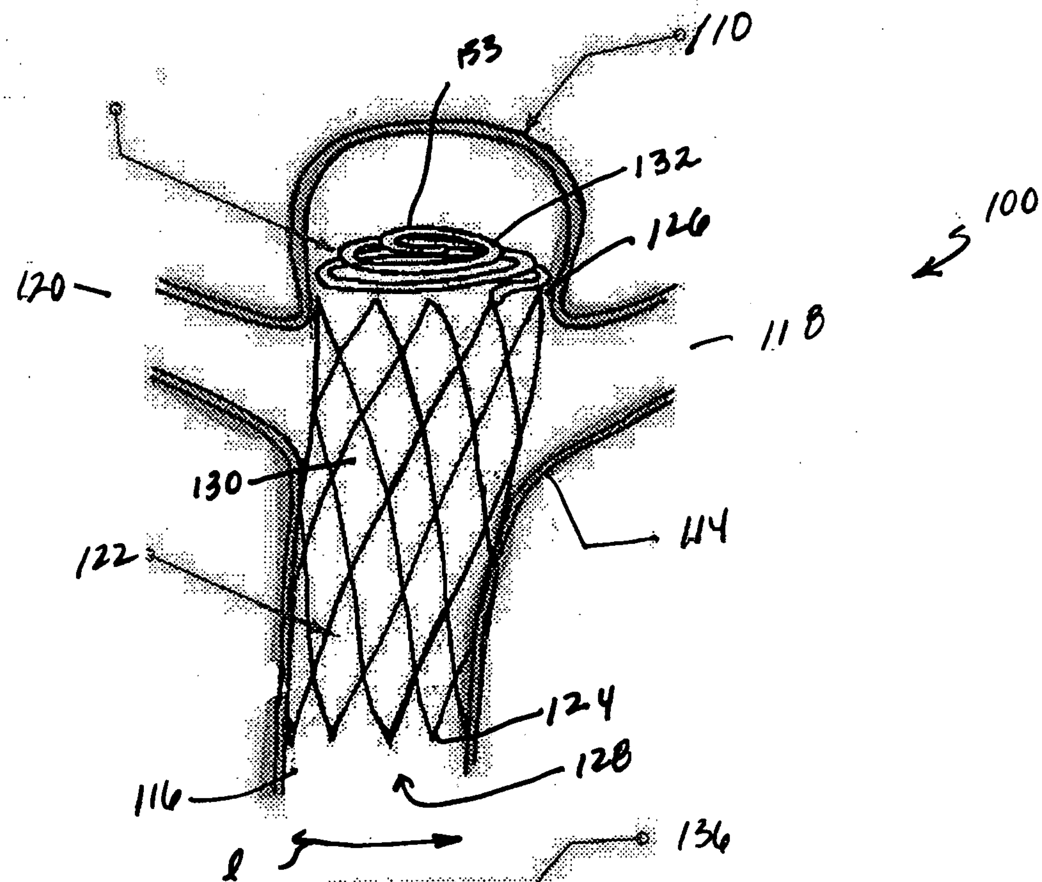
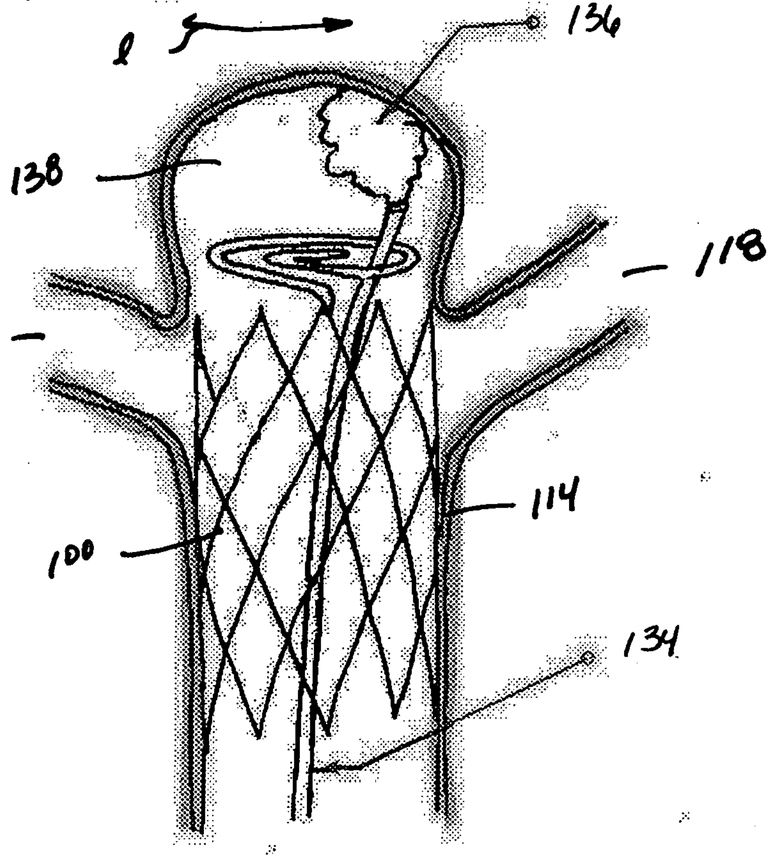


Fig 21



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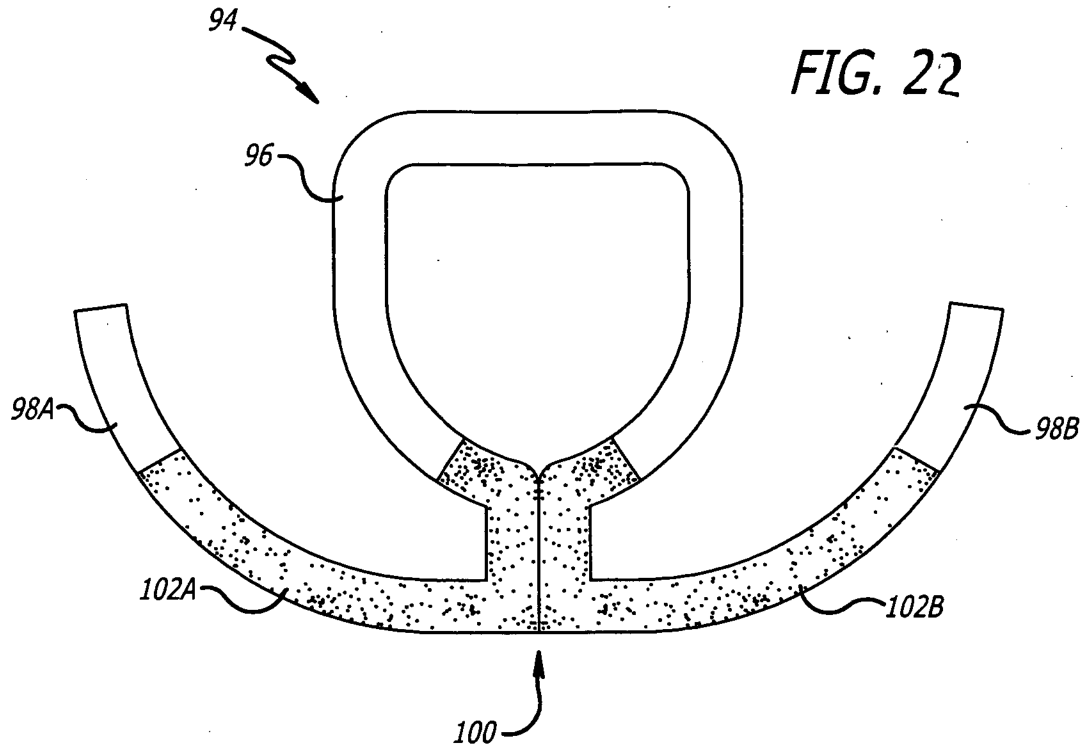
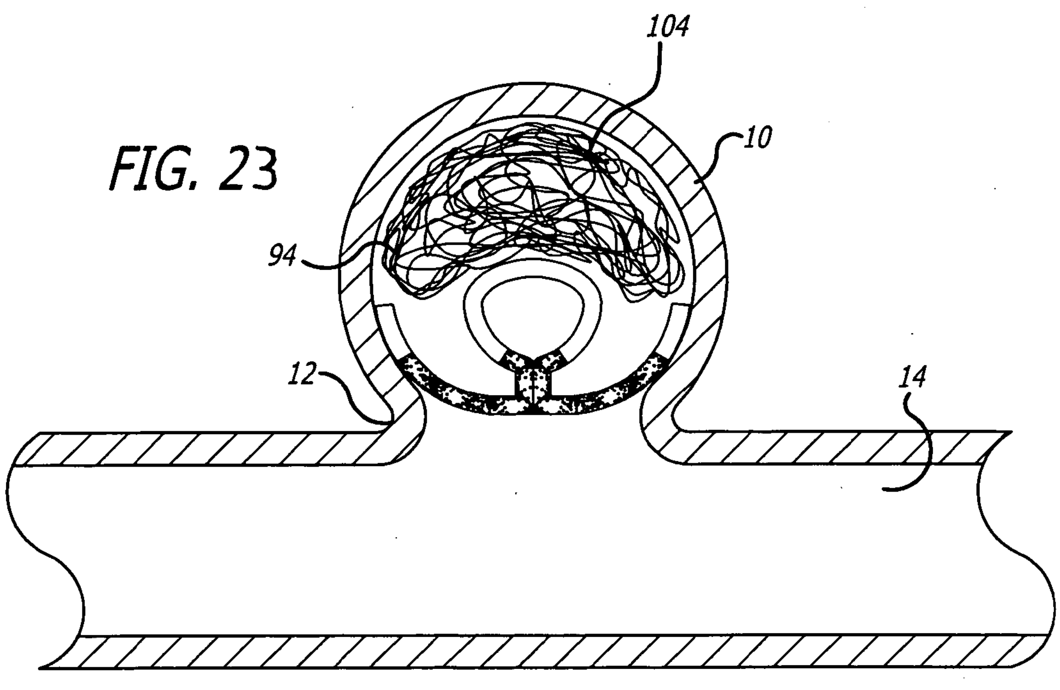


FIG. 22

FIG. 23



US006231597B1

(12) **United States Patent**
Deem et al.

(10) **Patent No.: US 6,231,597 B1**
(45) **Date of Patent: May 15, 2001**

(54) **APPARATUS AND METHODS FOR SELECTIVELY STENTING A PORTION OF A VESSEL WALL**

(76) Inventors: **Mark E. Deem**, 240-C Liberty St., San Francisco, CA (US) 94114; **Timothy W. Malisch**, 6217 N. Meredith Ave., Chicago, IL (US) 60646

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/250,710**

(22) Filed: **Feb. 16, 1999**

(51) **Int. Cl.**[7] **A61M 25/092**
(52) **U.S. Cl.** **623/1.12**; 623/1.11; 606/108
(58) **Field of Search** 606/198, 108, 606/200, 151, 153, 154, 190, 191, 195; 623/1.12, 1.11, 1.23

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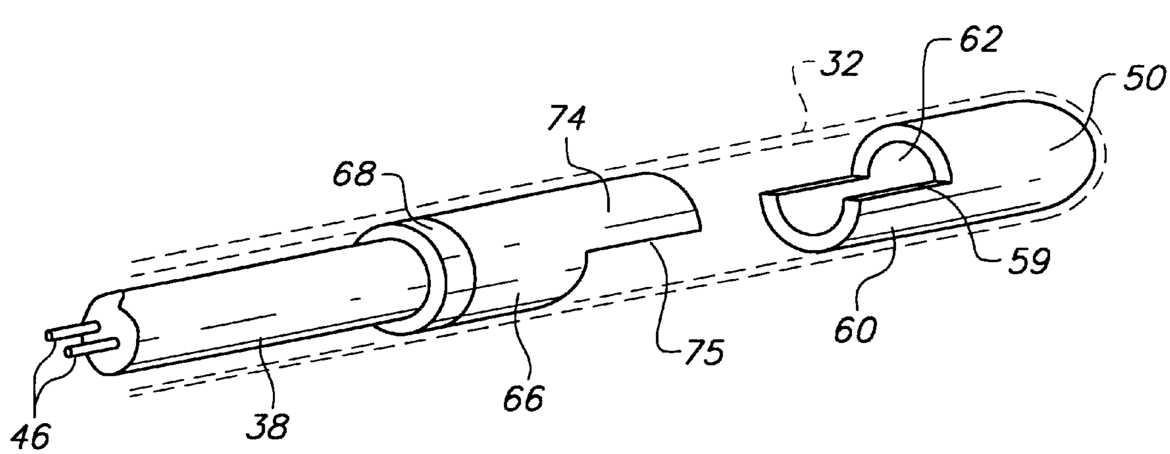
Primary Examiner—Michael H. Thaler
(74) *Attorney, Agent, or Firm*—Fish & Neave; Nicola A. Pisano

(57) **ABSTRACT**

Methods and apparatus for treating vascular abnormalities in highly tortuous vessels are provided comprising a stent having at least one end region that engages a first portion of a circumference of a vessel in a region adjacent to an abnormality to anchor the stent, and a mid-region that engages a second portion of the circumference of the vessel wall to span the abnormality, the second portion having a smaller circumferential extent than the first portion. The mid-region includes a plurality of members that span the abnormality and form a lattice that occludes the abnormality. A delivery system also is provided to deliver the stent within a parent artery and orient the mid-region of the stent to span the abnormality.

25 Claims, 5 Drawing Sheets



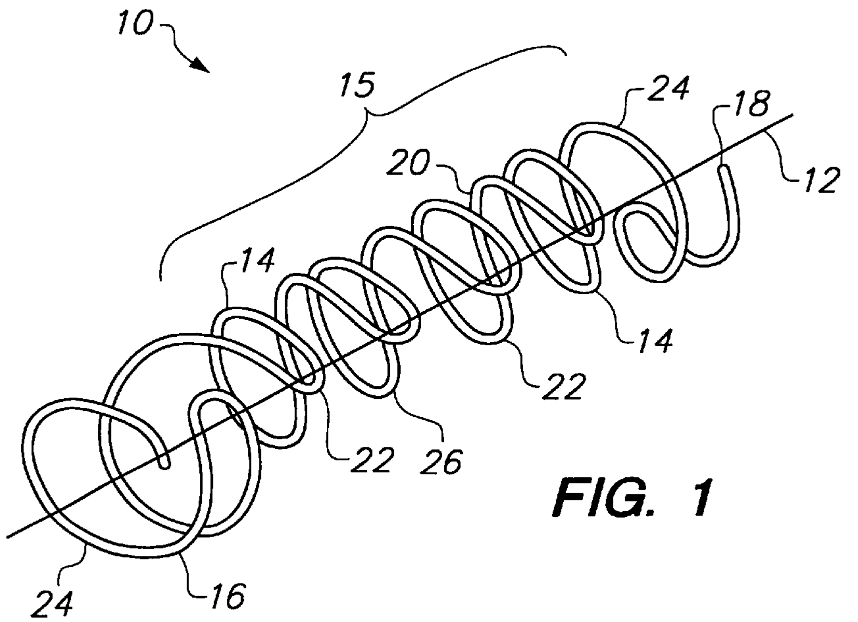
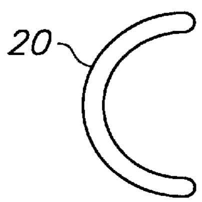


FIG. 1



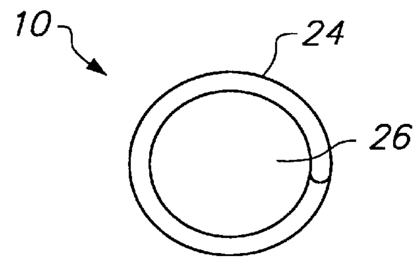


FIG. 3

FIG. 2

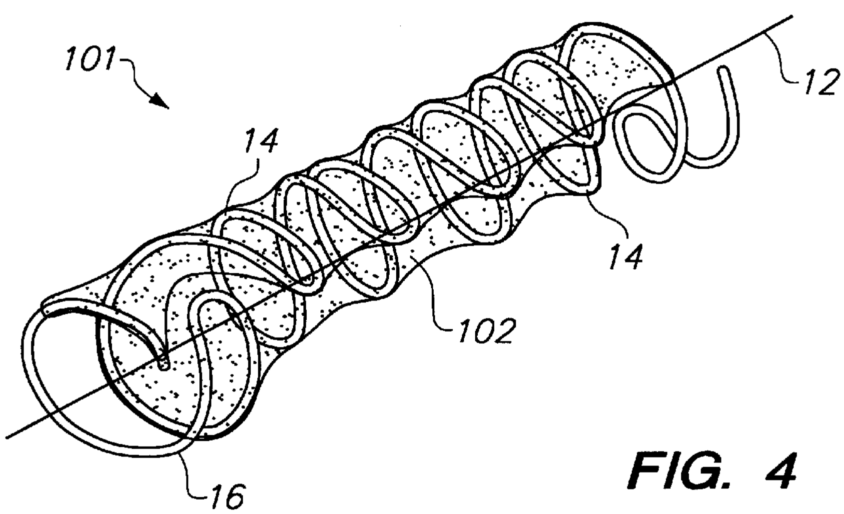


FIG. 4

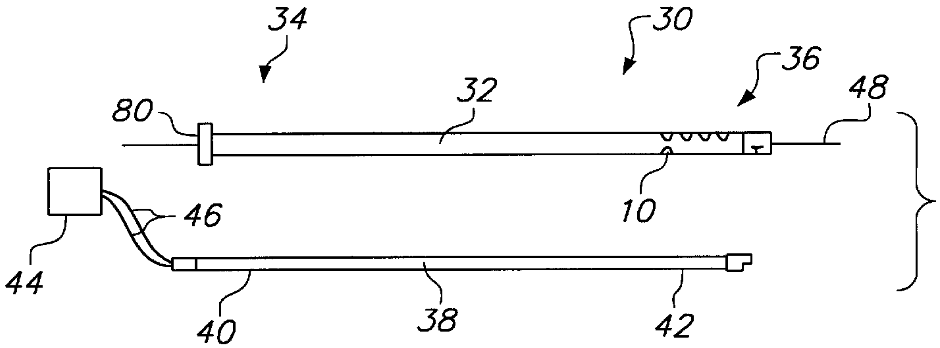


FIG. 5

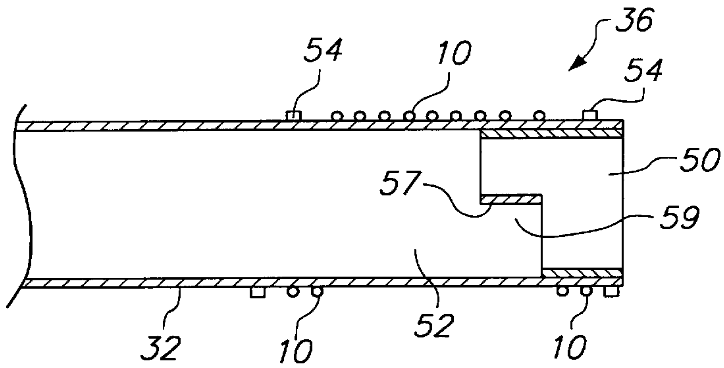


FIG. 6

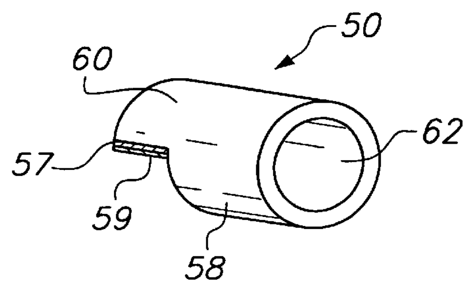


FIG. 7

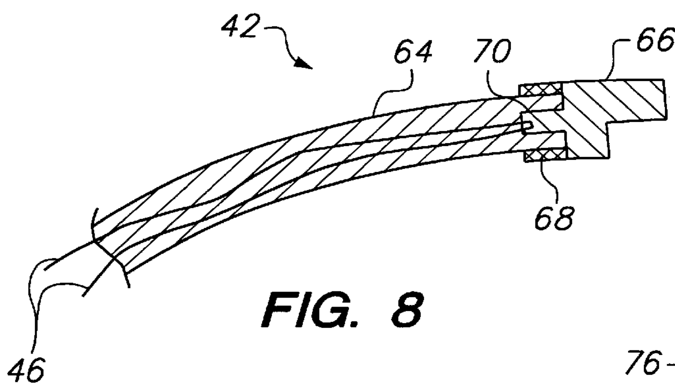


FIG. 8

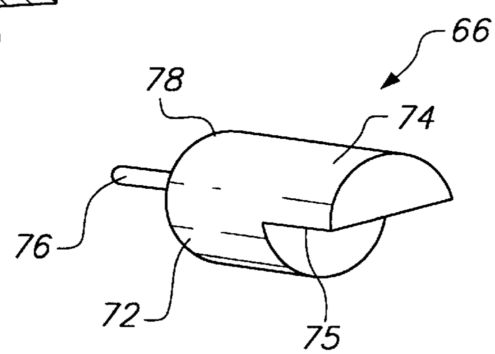


FIG. 9

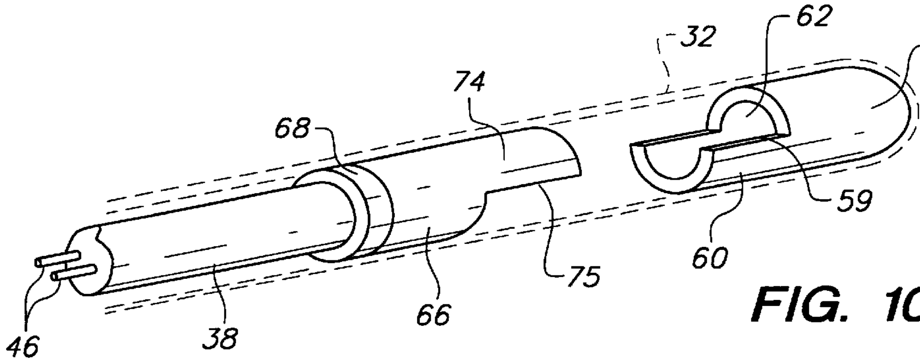


FIG. 10

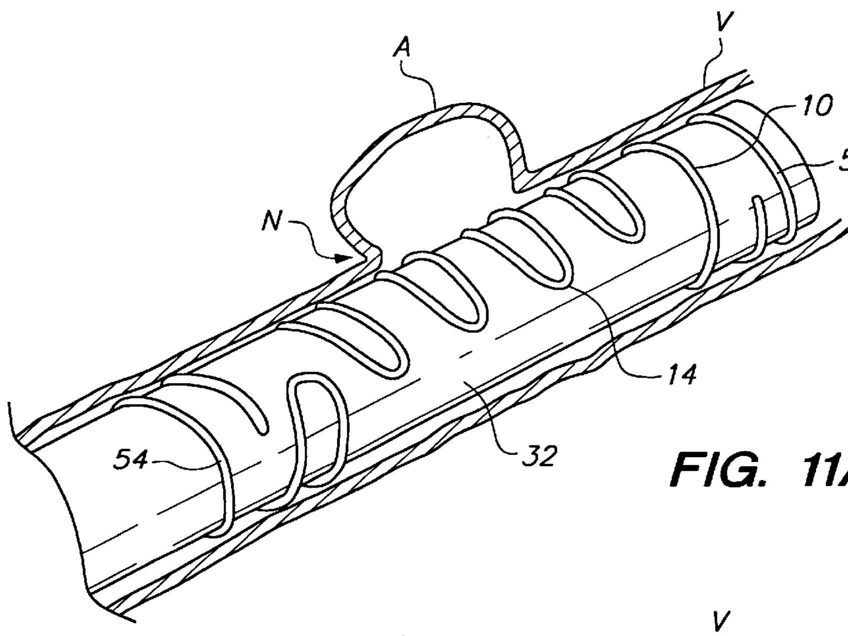


FIG. 11A

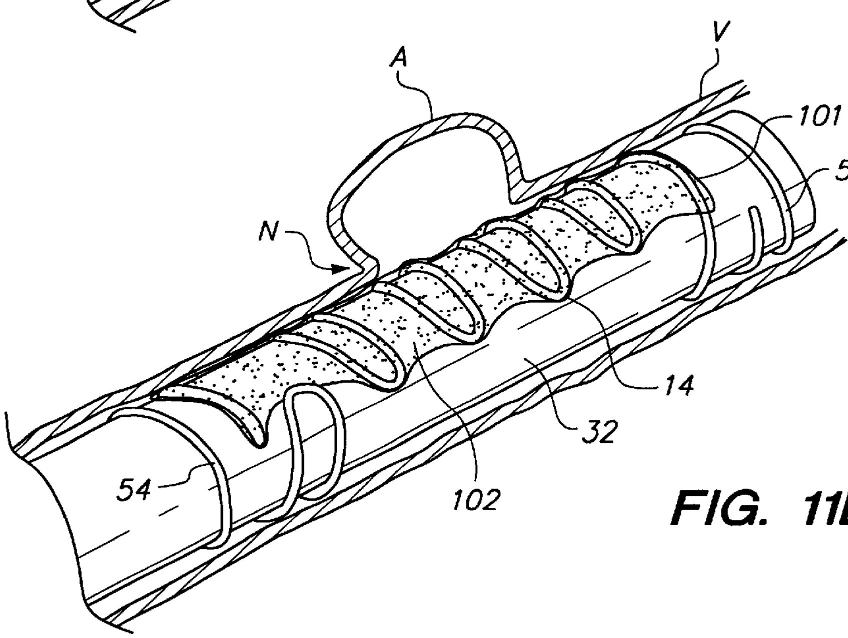


FIG. 11B

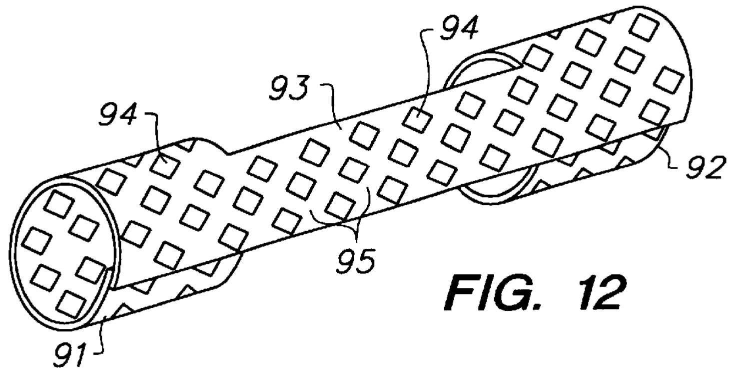


FIG. 12

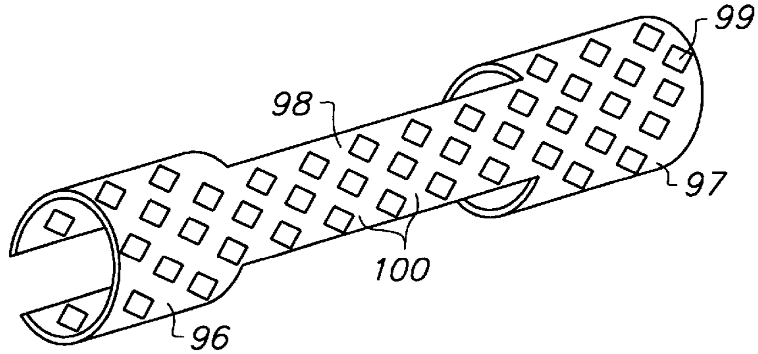


FIG. 13

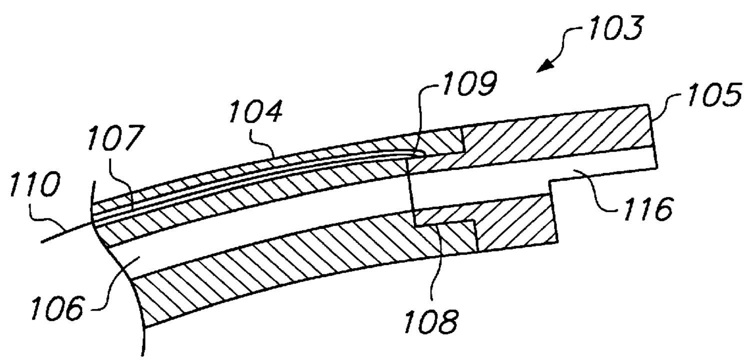


FIG. 14

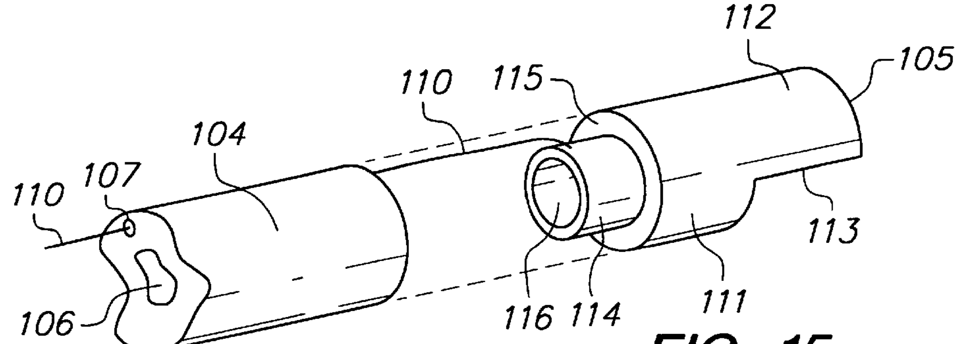


FIG. 15

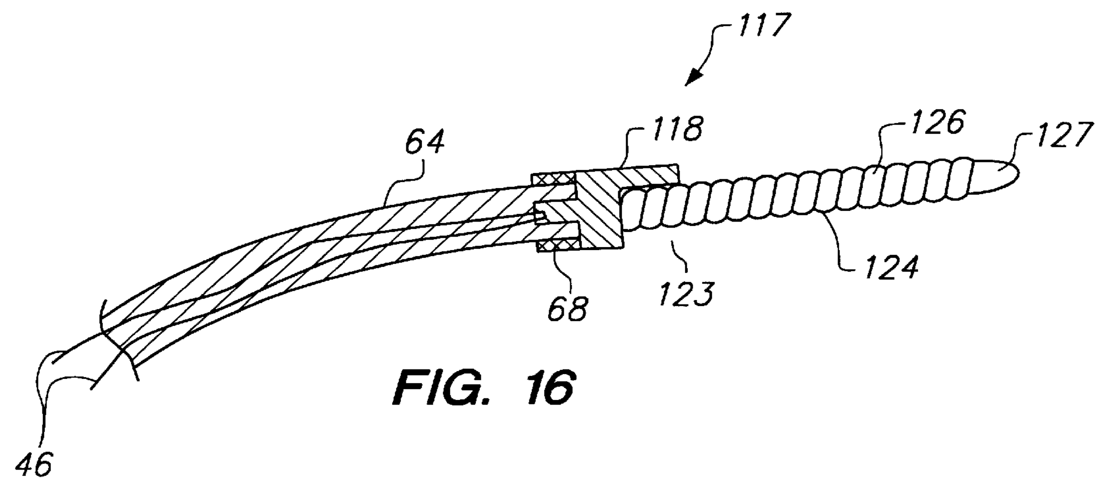


FIG. 16

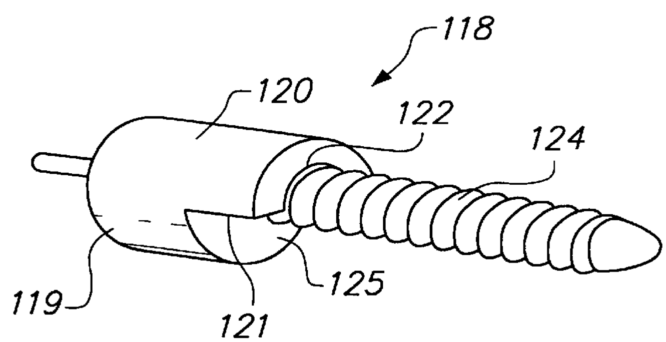


FIG. 17

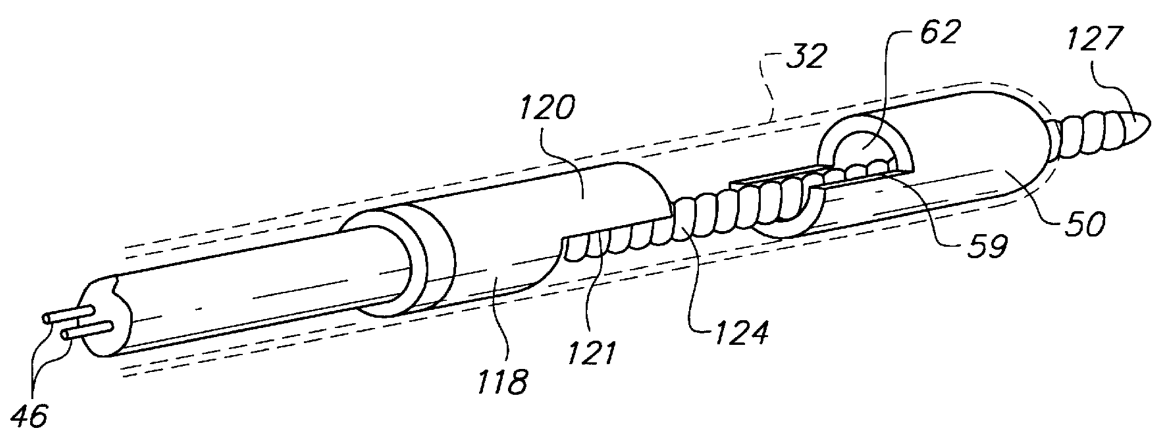


FIG. 18

APPARATUS AND METHODS FOR SELECTIVELY STENTING A PORTION OF A VESSEL WALL

FIELD OF THE INVENTION

The present invention relates to apparatus and methods for treating abnormalities or disease states in tortuous vessels. In particular, this invention relates to stents and delivery systems used to selectively support portions of a vessel wall, such as for treating aneurysms and vascular dissections.

BACKGROUND OF THE INVENTION

Some forms of vascular abnormality or disease states, such as aneurysms and vascular dissections, affect only portions of a vessel. The term "abnormality," as used herein, refers to any damage or disease state that affects a portion of a vessel wall. An aneurysm, for example, is an area within an artery where the artery wall integrity has become compromised by age, disease or trauma. As a result, blood pressure within the artery causes a portion of the artery wall to bulge or balloon. The portion of the aneurysm attached to the undeformed wall of the parent artery is called the "neck," and the bulbous pouch of the aneurysm is called the "dome." The dome is considerably thinner and weaker than the undeformed parent artery wall, and therefore is much more prone to rupture.

A vascular dissection describes vessel damage in which a portion of a vessel wall delaminates, and a flap of vascular tissue may extend into and partially occlude blood flow in the parent artery. In each of these different types of vascular abnormalities, a portion of a vessel wall is damaged, but the remaining vessel wall is otherwise healthy.

Vascular abnormalities can rupture and result in debilitating injury or death, depending on the size and location of the rupture and the amount of extra-arterial bleeding. For example, an aneurysm located in the brain is called a cerebral aneurysm, and hemorrhagic stroke results when a cerebral aneurysm ruptures. In addition to the risk of stroke, large aneurysms located in certain regions of the brain may result in neurologic problems due to so called "mass effect." This effect is characterized by the enlarged blood filled dome pressing upon important areas of the brain, and may be manifested by symptoms such as seizure, or impaired speech or vision.

Previously known methods for treating cerebral aneurysms include extravascular and endovascular techniques. Extravascular methods require delicate brain surgery to place a clip across the neck of the aneurysm to effectively exclude the dome from blood flow through the undeformed parent artery. Such surgical treatments can be associated with high trauma, long recovery times, incomplete recovery of all neurologic functions, morbidity and mortality associated with open brain surgery. Additionally, aneurysms located in some extremely sensitive areas, such as those surrounding the brain stem, may be inoperable due to the high risk of mortality.

Endovascular techniques, in contrast, treat aneurysms using a microcatheter positioned within the aneurysm or the parent artery. U.S. Pat. No. 5,122,136 to Guglielmi et al. describes one such previously known endovascular technique using a device commonly called a "Guglielmi Detachable Coil" (GDC). A GDC comprises a soft pliable coil made from platinum or platinum alloy that is soldered to a stainless steel coil and push wire. The stainless steel coil and push wire are used to position the platinum coil in the dome of the aneurysm, and position the junction between platinum coil and stainless steel coil near the neck of the aneurysm. A direct current (DC) is applied to the push wire, stainless steel coil and platinum coil to form a thrombogenic mass within the dome and thereby occlude the aneurysm.

By exposing the junction between the platinum coil and its push wire coil to blood and continuing to apply electric current to the push wire, the exposed portion of the stainless steel coil electrolytically dissolves. The remaining portion of the stainless steel coil and push wire then may be withdrawn from the artery, leaving the platinum coil within the dome. Depending on the size of the aneurysm, many such coils (typically from 5 to 20) may need to be placed within the dome to prevent blood from entering the aneurysm. Because pressure on the fragile dome is reduced, the risk of rupture is eliminated or greatly reduced.

Endovascular treatment permits access to vascular lesions through percutaneous introduction of microcatheters through the femoral artery, and therefore involves less patient trauma than an open surgical approach. This often results in a faster recovery and reduced morbidity and mortality. Drawbacks of GDC techniques include patient selection issues—the neck of the aneurysm must be of a sufficient size and orientation to allow coil entry, but prevent coil migration after detachment. Because multiple devices often must be placed directly in the fragile dome, each device introduction risks rupturing the dome due to mechanical trauma induced by the device.

U.S. Pat. No. 5,135,536 to Hillstead describes a stent for treating occlusive vascular disease comprising an expandable wire tube having a reduced diameter for transluminal placement. Once the stent is positioned within a vessel, a balloon catheter is used to expand the stent to support and reinforce the full circumference of the vessel. Such prior art stents typically have high radial strength to resist collapse due to vessel disease. U.S. Pat. No. 5,314,444 to Gianturco describes a stent having similar construction and operation.

Such previously known devices are not suitable for treating vascular abnormalities, such as aneurysms, occurring in highly tortuous vessels. For example, previously known endovascular stents are designed to provide high radial strength when deployed, and therefore generally are too rigid to negotiate the tortuous anatomy of cerebral vessels. In addition, because a stent, once deployed, is often overgrown by thick layer of vessel endothelium, a phenomenon referred to as "neointimal hyperplasia," there is some reduction of the vessel flow area after placement of the stent. Such reduction in flow area may cause an unacceptable reduction of blood flow in cerebral arteries. Some researchers believe that the higher the percent coverage of an artery by a stent, the more hyperplasia will occur.

As a result of the drawbacks of previously known endovascular techniques, it is desirable to find an alternative solution for treating vessels. In Wakhloo et al., "Self-Expanding and Balloon-Expandable Stents in the Treatment of Carotid Aneurysms: An Experimental Study in a Canine Model," *Am. J. Neuroradiology*, 15:493–502 (1994), the authors describe the feasibility of placing a stent across a portion of the neck of an aneurysm to alter the hemodynamics and therefore induce spontaneous clotting of stagnant blood within the dome. Those authors further postulated that the struts of the stent covering the neck of the aneurysm may provide a lattice for the growth of new endothelial cells across the neck, permanently excluding it from blood flow through the parent artery. Shrinking the aneurysm and resorption of blood within the aneurysm are expected to follow, thus preventing long-term mass effect problems.

In view of the foregoing, it would be desirable to provide methods and apparatus to enable a stent to be atraumatically and transluminally inserted into highly tortuous vessels, such as the cerebral arteries.

It further would be desirable to provide methods and apparatus for deploying a stent that spans a portion of a vessel to provide a lattice for the growth of new endothelial cells across the portion.

It also would be desirable to provide methods and apparatus comprising a stent having sufficient radial strength to resist downstream migration within the parent artery, but which is less subject to narrowing of the vessel flow area.

SUMMARY OF THE INVENTION

In view of the foregoing, it is an object of this invention to provide methods and apparatus to enable a stent to be atraumatically and transluminally inserted into highly tortuous vessels, such as the cerebral arteries.

It is another object of this invention to provide methods and apparatus for deploying a stent that spans a portion of an vessel to provide a lattice for the growth of new endothelial cells across the portion.

It is a further object of the present invention to provide methods and apparatus comprising a stent having sufficient radial strength to resist downstream migration within the parent artery, but which is less subject to narrowing of the vessel flow area.

These and other objects of the present invention are accomplished by providing a stent and a delivery system for implanting the stent. The stent comprises at least one end region that engages a first portion of a circumference of a vessel in a region adjacent to a vessel abnormality to anchor the stent, and a mid-region that extends over a second portion of the circumference of the vessel to span the abnormality, the second portion having a smaller circumferential extent than the first portion. The mid-region includes a plurality of members that span the abnormality and form a lattice that occludes the abnormality. The lattice also may be covered with a graft material, such as expanded polytetra fluoroethylene (PTFE), or polyester mesh. Because the mid-region extends over the smaller second portion of the circumference, the stent is highly flexible and may result in reduced narrowing of the flow area of the parent artery.

In accordance with the principles of the present invention, a delivery system is provided comprising a catheter that enables the mid-region of the stent to span the abnormality. In a preferred embodiment, the catheter comprises a flexible outer catheter on which the stent is releasably mounted, and an inner torsional catheter that selectively engages the outer catheter to rotate the stent to a desired orientation.

Methods of using the stent and delivery catheter of the present invention are also provided.

BRIEF DESCRIPTION OF THE DRAWINGS

Further features of the invention, its nature and various advantages will be more apparent from the accompanying drawings and the following detailed description of the preferred embodiments, in which:

FIG. **1** is a perspective view of an illustrative embodiment of a stent constructed in accordance with the principles of the present invention;

FIG. **2** is an end view of the stent of FIG. **1**;

FIG. **3** is a side view of a member forming the mid-region of the stent of FIG. **1**;

FIG. **4** is a perspective view of an alternative illustrative embodiment of a stent constructed in accordance with the principles of the present invention;

FIG. **5** is a side view of an illustrative embodiment of a delivery system constructed in accordance with the principles of the present invention;

FIG. **6** is a sectional view of a distal end of an outer catheter of the delivery system of FIG. **5**;

FIG. **7** is a perspective view, in isolation, of the first torsion gear of FIG. **6**;

FIG. **8** is a sectional view of an inner torsion catheter of the delivery system of FIG. **5**;

FIG. **9** is a perspective view of the second torsion gear of FIG. **8**;

FIG. **10** is a partial cutaway view of the delivery system of FIG. **5**;

FIG. **11A** is a partial sectional view of the stent of FIG. **1** and the delivery system of FIG. **5** disposed within a vessel;

FIG. **11B** is a partial sectional view of the stent of FIG. **4** and the delivery system of FIG. **5** disposed within a vessel;

FIG. **12** is a perspective view of an alternative embodiment of the stent of the present invention;

FIG. **13** is a perspective view of another alternative embodiment of the stent of the present invention;

FIG. **14** is a sectional view of an alternative inner torsion catheter of the present invention;

FIG. **15** is a partial cutaway view of the inner torsion catheter of FIG. **14**;

FIG. **16** is a sectional view of another illustrative inner torsion catheter of the delivery system of FIG. **5**;

FIG. **17** is a perspective view of the second torsion gear of FIG. **16**; and

FIG. **18** is a partial cutaway view of the delivery system of FIG. **5** using the inner torsion catheter of FIG. **16**.

DETAILED DESCRIPTION OF THE INVENTION

The present invention provides methods and apparatus for negotiating highly tortuous vessels to treat abnormalities located therein, without suffering from the drawbacks of previously known devices. More particularly, apparatus constructed in accordance with the principles of the present invention includes a stent having at least one end portion that engages a first portion of a circumference of a vessel to anchor the stent, and a mid-region having a plurality of members that extend over a second portion of the circumference of a vessel to span the abnormality, the second portion having a smaller circumferential extent than the first portion. Although the mid-region of the stent is highly flexible, care must be taken to orient the mid-region relative to the abnormality. Accordingly, a delivery system is provided for orienting the stent within the vessel during deployment.

Referring now to FIG. **1**, an illustrative stent constructed in accordance with the principles of the present invention is described. Stent **10**, shown in FIG. **1** in a deployed state, has a longitudinal axis **12**, mid-region **15** comprising a plurality of elements **14**, and first end **16** and second end **18**. Elements **14** of mid-region **15** are formed of a plurality of curved sections **20** joined by a plurality of bends or cusps **22**. First and second ends **16** and **18** include curved sections **24**.

When deployed in a vessel, curved sections **24** and **20** preferably have a convex outer surface and engage a first portion and a second portion, respectively, of the circum-

ference of the vessel, the second portion smaller than the first portion. As shown in FIG. **1**, curved sections **24** engage a first portion equal to the full circumference of the vessel, whereas curved sections **20** engage a second portion less than the full circumference (e.g., one-quarter, one half or three-quarters, etc.). Curved sections **20** and **24** preferably are oriented generally perpendicularly to longitudinal axis **12**.

As illustrated in FIGS. **2** and **3**, curved sections **24** form a tubular member having central opening **26**, whereas curved sections **20**, which have the same deployed diameter as curved sections **24**, extend over only a portion of the circumference of the vessel. Accordingly, when stent **10** is deployed in a parent vessel, curved sections **24** at first and second ends **16** and **18** engage the interior surface of a parent vessel adjacent to the neck of the aneurysm, whereas curved sections **20** form a plurality of members that span the abnormality to promote clotting and endothelial growth. Advantageously, because mid-region **15** does not extend over the entire circumference of the vessel when deployed, stent **10** is highly flexible and provides less resistance to blood flow through the parent artery.

Stent **10** preferably is constructed of a shape-memory material such as nickel-titanium alloy (nitinol) having an austenite phase transition temperature slightly above body temperature. In this case, the stent may be cooled into the martensite phase and compressed to a reduced delivery diameter, and conditioned to undergo a heat-activated phase transformation to a deployed, expanded state when heated to a temperature slightly above body temperature. Alternatively, an electric current may be applied to heat the stent to a temperature at which it transitions to the austenite phase, and assumes an expanded shape. Alternatively, the transformation temperature may be set below body temperature, and the stent mechanically constrained.

Stent **10** may be formed, for example, by wrapping a nitinol wire around a mandrel template, and then conditioning the wire through a series of heat treatments in accordance with methods that are per se known. Alternatively, stent **10** may be fabricated from either nitinol or stainless steel tubing or sheets using previously known electron discharge machining (EDM), chemical etching, or laser cutting techniques. As a further alternative, stent **10** may be formed from a biocompatible or bioerodible polymer.

FIG. **4** illustrates an alternative embodiment of a stent constructed in accordance with the principles of the present invention. Stent **101** is similar to stent **10**, but includes cover **102** that spans elements **14** and is disposed about a portion of the circumference of stent **101**. Cover **102** may comprise a typical graft material, such as polyester or expanded PTFE, and may be applied to an exterior or interior surface of elements **14** using a biocompatible adhesive or sutures. When stent **101** is deployed in a parent vessel, cover **102** is oriented to span the abnormality to promote clotting and endothelial growth.

Referring to FIG. **5**, delivery system **30** for deploying a stent of the present invention is described. As will be readily apparent, the delivery system of the present invention advantageously may be used whenever it is desired to align a feature of a device with a region of a vessel. Delivery system **30** includes outer catheter **32** having proximal end **34** and distal end **36**, inner torsion catheter **38** having proximal end **40** and distal end **42**, and controller **44** coupled to proximal end of inner torsion catheter **38** by insulated wires **46**.

As illustrated in FIG. **6**, outer catheter **32** preferably comprises a highly flexible material, such as polyethylene, silicone, nylon, polyester or polyurethane, having central lumen **52** that accepts guide wire **48** and has first torsion gear **50** mounted on distal end **36**. First torsion gear **50**, shown in isolation in FIG. **7**, preferably comprises a radiopaque and conductive metal, metal composite or metal alloy, and includes cylindrical portion **58**, stepped portion **60** having engagement surface **59**, and lumen **62** extending through portions **58** and **60**. Stent **10** is mounted adjacent to distal end **36** of catheter **32**, and/or first torsion gear **50**, for example, by a thermally activated adhesive or polymer, or electrically erodible wire. Alternatively, a retractable sheath could retain stent **10** on catheter **32**, allowing stent **10** to expand when the sheath is retracted.

Distal end **36** of outer catheter **32** also preferably includes radio-opaque marker bands **54** disposed on outer surface **56**, which may be used to identify the longitudinal location of stent **10** relative to the neck of a target aneurysm, and longitudinally-oriented marker band **57** on first torsion gear **50**. Marker band **57** enables the physician to determine the circumferential orientation of stent **10** relative to the neck of an abnormality, as described in greater detail below.

Referring to FIG. **8**, distal end **42** of inner torsion catheter **38** is described. Inner torsion catheter **38** comprises tubular member **64** having second torsion gear **66** coupled to its distal end by clamp ring **68**. Insulated wires **46** extend from second torsion gear **66** and through tubular member **64** to controller **44**. Tubular member **64** is flexible in the longitudinal direction, but is sufficiently rigid to apply torque to second torsion gear **66**. Tubular member **64** preferably comprises a combination of braided metal and metal alloy wires enclosed within a polymer jacket and lubricious coating, or alternatively, a helical coil and metal alloy wires covered with a polymer jacket and lubricious coating. Tubular member **64** includes a lumen or bore **70** for accepting a shank portion of second torsion gear **66**.

With respect to FIG. **9**, second torsion gear **66**, shown in isolation, includes cylindrical portion **72**, stepped portion **74** having engagement surface **75**, and shank **76** extending from end face **78** of cylindrical portion **72**. Shank **76** fits within bore **70** of tubular member **64** so that when clamp ring **68** is applied, it secures tubular member **64** to shank **76**.

Second torsion gear **66** preferably comprises an electrically conductive metal, metal composite or metal alloy that is resistively heated when a radio-frequency ("RF") power is applied from controller **44** through insulated wires **46**. In this manner, second torsion gear **66** may be selectively resistively heated by controller **44**, so that heat generated in second torsion gear **44** is conducted to and melts the thermally activated adhesive or polymer retaining stent **10** on outer catheter **32**. Alternatively, second torsion gear may be configured to electrically couple to first torsion gear **50**, to deliver power to an electrically erodible wire that retains stent **10** on outer catheter **32**.

As depicted in FIG. **10**, engagement surface **75** of second torsion gear **66** is configured to engage engagement surface **59** of first torsion gear **50**, so that rotation of inner torsion catheter **38** causes rotation of distal end **36** of catheter **32**. Accordingly, inner torsion catheter enables mid-region **15** of stent **10** to be oriented so that it spans the neck of an aneurysm.

Referring now to FIGS. **11**A and **11**B, illustrative methods of using the delivery system of FIG. **5** to deploy a preferred embodiment of the stent of the present invention are described. First, outer catheter **32** is percutaneously and transluminally advanced over a guide wire to dispose distal end **36** in a portion of vessel V containing aneurysm A using

known radiological techniques. Once stent **10** is disposed across neck N of aneurysm A, for example, by determining the location of marker bands **54** with a fluoroscope, the guide wire is withdrawn.

Inner torsion catheter **38** is inserted through hemostatic coupling **80** of outer catheter **32** and then advanced and rotated until second torsion gear **66** engages with first torsion gear **50**. Inner torsion catheter **38** is then rotated, for example, as guided by radio-opaque marker band **57**, until the convex portion of mid-region **15** is aligned with and spans neck N of aneurysm A, as depicted in FIG. **11**A. More specifically, rotation of inner torsion catheter **38** and outer catheter **32** may be as a unit. Alternatively, because outer catheter **32** is more flexible than inner torsion catheter **38**, relative movement of inner torsion catheter **38** within outer catheter **32** may simply cause the distal end of the outer catheter to twist while the proximal end of outer catheter **32** remains stationary.

Controller **44** is then activated to cause an RF current to flow through second torsion gear **66**. In an embodiment where stent **10** is affixed to distal end **36** of outer catheter **32** by a thermally activated adhesive or polymer, for example, a low temperature biocompatible wax, the RF power delivered to second torsion gear **66** causes resistive heating of the distal end of the catheter, thereby melting the thermally activated adhesive and permitting the stent to expand to its deployed diameter. Delivery system **30** is then withdrawn, leaving stent **10** with mid-region **15** disposed across neck N of aneurysm A. Stent **10** serves to alter the hemodynamics within aneurysm A to cause it to clot, and acts as a scaffold for endothelial growth that excludes aneurysm A from vessel V.

Alternatively, in an embodiment where stent **10** is retained on distal end **36** by an electrically erodible wire coupled to first torsion gear **50**, RF power supplied by controller **44** may be delivered to and cause stent **10** to undergo a thermally activated phase change to expand to its deployed state. Applying additional power causes the erosion of the electrically erodible wire.

FIG. **11**B illustrates deployment of stent **101** of FIG. **4**. As shown in FIG. **11**B, during deployment, inner torsion catheter **38** is rotated until cover **102** is aligned with and spans neck N of aneurysm A. Once stent **101** expands to its deployed diameter, cover **102** acts as a scaffold for endothelial growth that excludes aneurysm A from vessel V.

Other arrangements of insulating wires **46** and controller **44** will be apparent to one of skill in the art of interventional catheter design. For example, in other embodiments, other release mechanisms may be employed to release stent **10** from distal end **36** of outer catheter **32**, such as the pull-wire arrangement described in U.S. Pat. No. 5,443,500 to Sigwart, which is incorporated herein by reference.

In still other embodiments, stent **10** may comprise an elastically expandable, plastically deformable or super-elastic material, rather than thermally-activated material, and may be constructed using other shapes than the arcuate wire portions of the embodiment of FIG. **1**.

For example, as depicted in FIG. **12**, stent **10** may comprise first and second coil-sheet portions **91** and **92**, respectively, such as described in the above-incorporated patent to Sigwart, interconnected by mid-region **93**. Coil-sheet portions **91** and **92** and mid-region **93** preferably comprise a mesh having a plurality of openings **94**, so that the lattice formed by openings **94** constitutes a plurality of intersecting members **95**. Coiled sheet portions **91** and **92** may be wound to a reduced diameter for transluminal delivery, and then expanded (or permitted to self-expand) once positioned within a vessel so that mid-region **93** spans the abnormality. As shown in FIG. **12**, when deployed, coiled-sheet portions **91** and **92** engage a first portion equal to the full circumference of the vessel, whereas mid-region **93** engages a second portion of the circumference, the second portion less than the first portion.

As shown in FIG. **13**, stent **10** alternatively may comprise first and second coiled expansile portions **96** and **97**, respectively, interconnected by mid-region **98**. Coil-ring portions **96** and **97** and mid-region **98** preferably comprise a mesh having a plurality of openings **99**, so that the lattice formed by openings **99** constitutes a plurality of intersecting members **100**. When deployed, coil-ring portions **96** and **97** engage a first portion less than a full circumference of the vessel, and mid-region **98** engages a second portion of the circumference, the second portion less than the first portion.

For certain applications, it may be desirable to keep a guide wire or a guide wire tip in the vessel during stent placement. In particular, the guide wire or guide wire tip may provide additional stability during torquing of the inner and outer catheters. FIGS. **14** and **15** illustrate a distal end of an alternative embodiment of an inner torsion catheter that permits catheter delivery and deployment with a guide wire in the vessel.

As shown in FIG. **14**, inner torsion catheter **103** comprises tubular member **104** having second torsion gear **105** coupled to its distal end. Tubular member **104** includes central lumen **106**, peripheral lumen **107** and bore **108**. Peripheral lumen **107** terminates at its distal end with opening **109** in a sidewall of bore **108**. Insulated wires **110** (one shown in FIG. **14**) extend from second torsion gear **105** and through peripheral lumen **107** to controller **44**. Tubular member **104** is flexible in the longitudinal direction, but is sufficiently rigid to apply torque to second torsion gear **105**. Tubular member **104** preferably comprises a combination of braided metal and metal alloy wires enclosed within a polymer jacket and lubricious coating, or alternatively, a helical coil and metal alloy wires covered with a polymer jacket and lubricious coating. Bore **108** accepts a shank portion of second torsion gear **105**.

As shown in FIGS. **14** and **15**, second torsion gear **105** includes cylindrical portion **111**, stepped portion **112** having engagement surface **113**, shank **114** extending from end face **115** of cylindrical portion **111** and lumen **116** extending through shank **114**, cylindrical portion **111** and stepped portion **112**. Shank **114** fits within bore **108** of tubular member **104** and is secured to tubular member **104** with a suitable adhesive, for example epoxy.

Second torsion gear **105** preferably comprises an electrically conductive metal, metal composite or metal alloy. Insulated wires **110** are electrically bonded to shank **114**, such as by soldering or crimping. Second torsion gear **105** is resistively heated when RF power is applied from controller **44** through insulated wires **110**.

FIGS. **16–18** illustrate a distal end of a further alternative embodiment of an inner torsion catheter having a guide wire tip. As shown in FIGS. **16** and **17**, second torsion gear **118** includes cylindrical portion **119**, stepped portion **120** having engagement surface **121** and semi-circular bore **122**, and guide wire tip **124** extending from front face **125** of cylindrical portion **119**. Guide wire tip **124** includes flexible coiled portion **126** and tapered tip **127**. Proximal end **123** of guide wire tip **124** is engaged in semi-circular bore **122** of stepped portion **120**. Coiled portion **126** preferably comprises an electrically insulative, flexible helical coil com-

prising a plastic or a metal alloy, such as stainless steel, having an electrically insulative cover. Tapered tip **127** may comprise a biocompatible material, such as nylon, disposed on the distal end of coiled portion **126**. Alternatively, guide wire tip **124** may comprise a short section of a conventional stainless steel guide wire having an electrically insulative cover.

Second torsion gear **118** preferably comprises an electrically conductive metal, metal composite or metal alloy that is resistively heated when a radio-frequency RF power is applied from controller **44** through insulated wires **46**. As shown in FIG. **18**, engagement surface **121** of second torsion gear **118** is configured to engage engagement surface **59** of first torsion gear **50**. Guide wire tip **124** extends through lumen **62** in first torsion gear **60**.

Although preferred illustrative embodiments of the present invention are described above, a person of ordinary skill in the art will understand that various changes and modifications may be made without departing from the invention. Applicants intend that the appended claims cover all such changes and modifications that fall within the true spirit and scope of the invention.

What is claimed is:

1. Apparatus for treating an abnormality in a vessel, the apparatus comprising:

a tubular member including an end region configured to circumferentially engage a first portion of the vessel adjacent to the abnormality;

a mid-region of the tubular member comprising a plurality of members having a convex outer surface that is configured to engage a second portion of the vessel, the second portion being circumferentially smaller than the first portion and less than a full circumference of the vessel, the plurality of members adapted to span the abnormality; and

a delivery system comprising a first catheter having a distal end adapted to support the tubular member and the mid-region, the first catheter having a lumen and a first gear disposed within the lumen for orienting the mid-region so that it spans the abnormality,

wherein a retractable sheath retains the tubular member on the first catheter.

2. The apparatus of claim **1** wherein the tubular member comprises arcuate portions interconnected by a plurality of bends or cusps.

3. The apparatus of claim **1** wherein the tubular member has a longitudinal axis, the plurality of members oriented generally perpendicular to the longitudinal axis.

4. The apparatus of claim **1** wherein the tubular member comprises a coiled sheet.

5. The apparatus of claim **4** wherein the coiled sheet and mid-region comprises a plurality of openings.

6. The apparatus of claim **1** wherein the first portion is substantially equal to the full circumference of the vessel.

7. The apparatus of claim **1** wherein the first portion is less than the full circumference of the vessel.

8. The apparatus of claim **1** wherein the plurality of members engage one-half of the circumference of the vessel.

9. The apparatus of claim **1** wherein the tubular member further comprises a shape memory metal alloy or biocompatible polymer.

10. The apparatus of claim **1** further comprising a graft material covering the mid-region.

11. The apparatus of claim **1**, wherein the first gear comprises a lumen that permits a guide wire to extend beyond the distal end of the first catheter into the vessel.

12. The apparatus of claim **1** further comprising a second catheter configured for insertion into the lumen of the first catheter, the second catheter having a distal end and a second gear disposed on the distal end, the second gear configured to engage the first gear when the second catheter is inserted in the lumen.

13. The apparatus of claim **12**, wherein: p**1** the second gear comprises a guide wire tip; and

the first gear comprises a lumen that permits the guide wire tip to extend beyond the distal end of the first catheter into the vessel.

14. Apparatus for deploying a prosthesis to treat a region of a vessel, the prosthesis having a feature that is adapted to be aligned with the region, the apparatus comprising:

a flexible catheter having a distal end adapted to support the prosthesis, a lumen and a first gear disposed within the lumen, the first gear rotating the flexible catheter to orient the feature so that it is aligned with the region;

a torsion catheter configured for insertion into the lumen of the flexible catheter, the torsion catheter comprising an electrical conductor, a distal end, and a second gear disposed on the distal end, the second gear configured to engage the first gear when the torsion catheter is inserted in the lumen; and

a controller that supplies radio-frequency power to the second gear via the electrical conductor.

15. The apparatus of claim **14**, wherein the first gear comprises a lumen that permits a guide wire to extend beyond the distal end of the flexible catheter into the vessel.

16. The apparatus of claim **14**, wherein:

the second gear comprises a guide wire tip; and

the first gear comprises a lumen that permits the guide wire tip to extend beyond the distal end of the flexible catheter into the vessel.

17. The apparatus of claim **14**, wherein:

the first gear comprises a cylindrical portion and a stepped portion having an engagement surface; and

the second gear comprises a cylindrical portion and a stepped portion having an engagement surface that mates with the engagement surface of the first gear.

18. The apparatus of claim **14**, wherein the first gear further comprises a longitudinally-oriented marker band.

19. The apparatus of claim **14** wherein the prosthesis is mounted on the catheter by a thermally activated adhesive or polymer.

20. The apparatus of claim **14** wherein the prosthesis is mounted on the catheter by an electrically erodible wire.

21. Apparatus for deploying a prosthesis to treat a region of a vessel, the prosthesis having a feature that is adapted to be aligned with the region, the apparatus comprising:

a flexible catheter having a distal end adapted to support the prosthesis, a lumen and a first gear disposed within the lumen, the first gear rotating the flexible catheter to orient the feature so that it is aligned with the region,

wherein a retractable sheath retains the prosthesis on the catheter.

22. A method of treating an abnormality at a treatment site within a vessel, the method comprising:

providing a stent having a tubular end region comprising at least one curved section having a convex outer surface that is configured to engage a first portion of the vessel, and a mid-region comprising a plurality of members having a convex outer surface that is configured to engage a second portion of the vessel, the second portion being circumferentially smaller than the first portion and less than a full circumference of the vessel;

providing a delivery system for deploying the stent, the delivery system comprising a first catheter having a distal end configured to support the stent, a lumen, and a first gear disposed within the lumen, and a second catheter having a proximal end, a distal end, and a second gear disposed on the distal end;

transluminally disposing the stent at the treatment site;

inserting the second catheter into the lumen of the first catheter;

engaging the second gear with the first gear;

aligning the mid-region of the stent so that the plurality of members span the abnormality, by rotating a proximal end of the second catheter using the first gear to rotate the distal end of the first catheter;

providing a controller that outputs a radio-frequency power; and

coupling the controller to the second catheter to release the stent from the distal end of the first catheter.

23. The method of claim **22** wherein a thermally activated adhesive or polymer retains the stent on the first catheter, and coupling the controller to the second catheter to release the stent from the distal end of the first catheter further comprises selectively resistively heating a portion of the first catheter to melt the adhesive or polymer to release the stent from the first catheter.

24. The method of claim **22** wherein an electrically erodible wire retains the stent on the first catheter, and coupling the controller to the second catheter to release the stent from the distal end of the first catheter further comprises delivering electrical power to the electrically erodible wire to release the stent from the first catheter.

25. A method of treating an abnormality at a treatment site within a vessel, the method comprising:

providing a stent having tubular end region comprising at least one curved section having a convex outer surface that is configured to engage a first portion of the vessel, and a mid-region comprising a plurality of members having a convex outer surface that is configured to engage a second portion of the vessel, the second portion being circumferentially smaller than the first portion;

providing a delivery system for deploying the stent, the delivery system comprising a first catheter having a distal end configured to receive the stent, a lumen, and a first gear disposed within the lumen;

transluminally disposing the stent at the treatment site;

aligning the mid-region of the stent so that the plurality of members span the abnormality by operating the first gear to rotate the distal end of the first catheter, and wherein a retractable sheath retains the stent on the first catheter; and

retracting the sheath to release the stent from the first catheter.

* * * * *

US005234456A

United States Patent [19]

Silvestrini

[11] Patent Number: 5,234,456

[45] Date of Patent: Aug. 10, 1993

[54] **HYDROPHILIC STENT**

[75] Inventor: **Thomas A. Silvestrini**, East Lyme, Conn.

[73] Assignee: **Pfizer Hospital Products Group, Inc.**, New York, N.Y.

[21] Appl. No.: **883,241**

[22] Filed: **May 7, 1992**

Related U.S. Application Data

[63] Continuation of Ser. No. 477,264, Feb. 8, 1990, abandoned.

[51] **Int. Cl.**[5] **A61M 29/02**

[52] **U.S. Cl.** **606/194**; 623/1; 604/96

[58] **Field of Search** 604/8, 96, 101, 264, 604/265, 280, 281, 285; 606/192, 194, 198, 108; 623/1, 12

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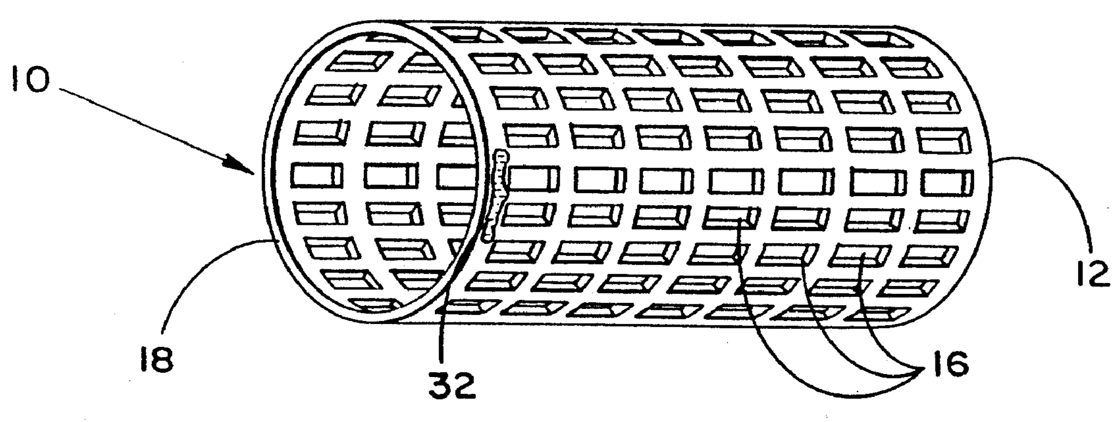
Assistant Examiner—Corrine Maglione
Attorney, Agent, or Firm—Peter C. Richardson; Lawrence C. Akers; Eric M. Lee

[57] **ABSTRACT**

A stent for placement within a body lumen and comprising a wall structure wherein at least a portion thereof is a hollow wall. The hollow wall has disposed therein a hydrophilic material which can be in the form of a gel, for example, which swells upon introduction of a liquid into the hollow wall to thereby achieve inflation thereof. The hollow wall is fabricated of a semi-permeable membrane whereby fluid from tissues surrounding the stent at the site of placement can pass through the membrane and swell the hydrophilic material to thereby inflate the hollow wall. A drug can be disposed with the hydrophilic material for release through the membrane at the site of stent placement. The entire wall structure of the stent can be a hollow wall, or the wall structure can incorporate both hollow and non-hollow wall portions such as hollow and solid fibers which are braided, woven or wound together.

12 Claims, 1 Drawing Sheet



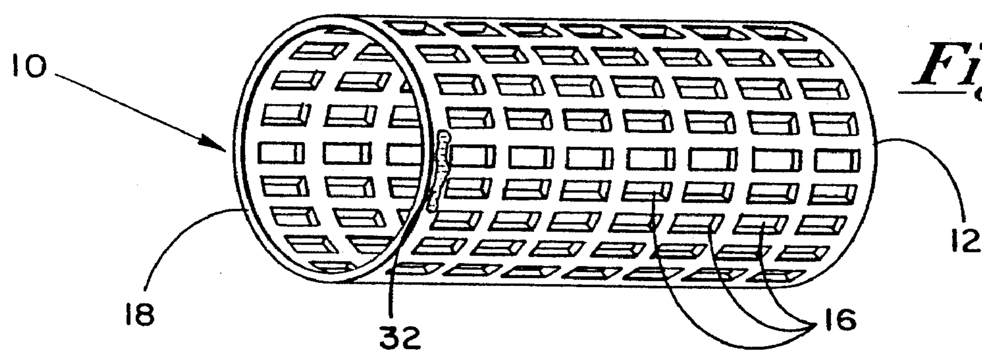


Fig.-1

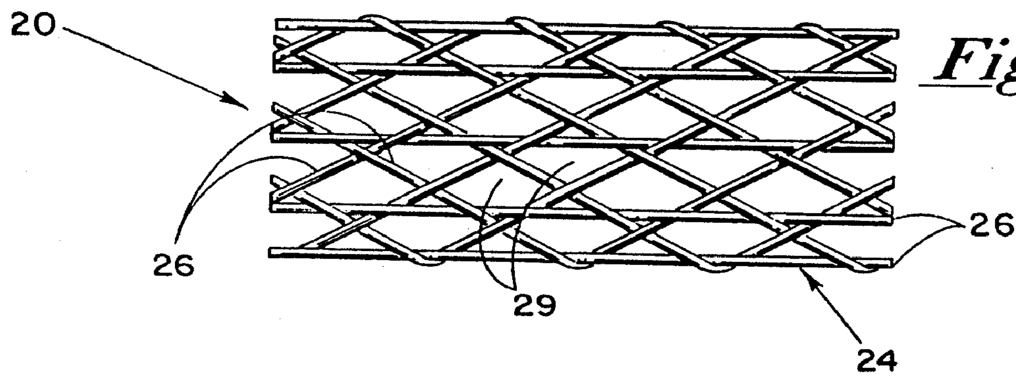


Fig.-2

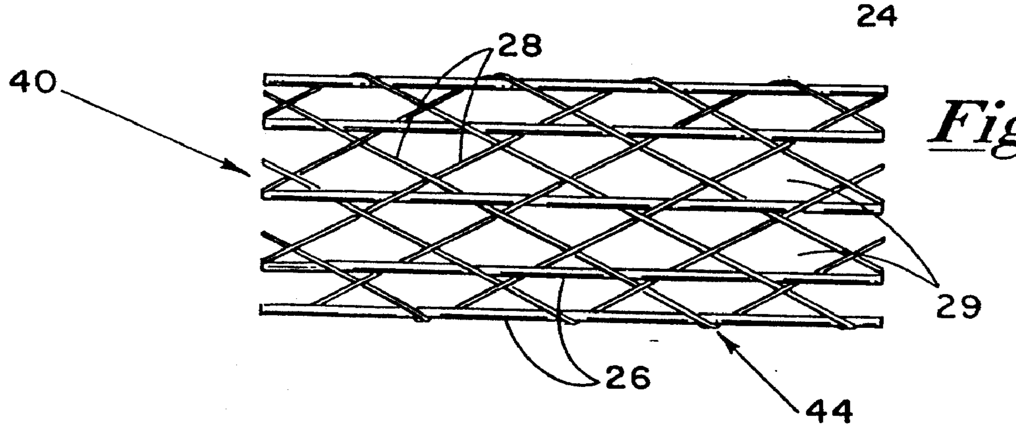


Fig.-3

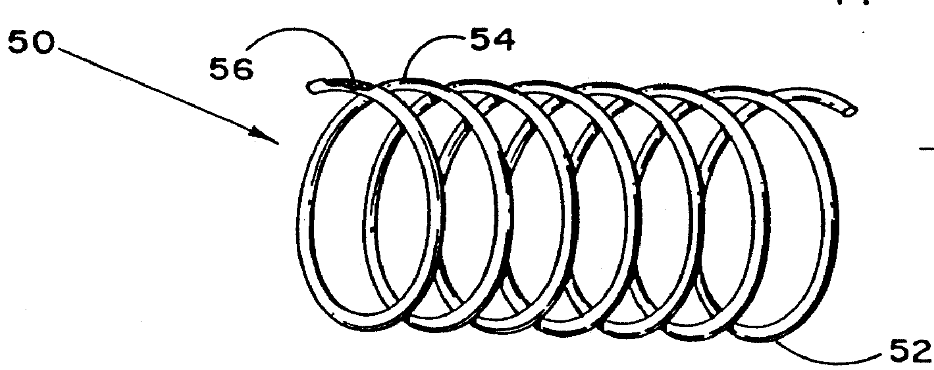


Fig.-4

HYDROPHILIC STENT

This is a continuation of application Ser. No. 477,264, filed on Feb. 8, 1990, now abandoned.

BACKGROUND OF THE INVENTION

This invention relates generally to stents employed to maintain in an open configuration a body lumen such as a duct or vessel, and in particular to a stent having a hollow and inflatable wall.

The employment of stents to maintain otherwise closed or occluded body lumens such as ducts or vessels, for example, in an open configuration is a well-recognized treatment procedure. Current commonly used stents include self-expanding stents as described in U.S. Pat. No. 4,655,771, for example, and stents which are expanded at the lumen site by a balloon which is inflated within the stent. In either case, the stents are usually constructed of metal, and therefore generally possess a degree of stiffness and a minimal pliability.

It is therefore a primary object of the present invention to provide a stent having a wall which is soft and pliable upon insertion, but which has the capability to provide the proper magnitude of stiffness and rigidity after placement at the site of treatment. Another object of the present invention is to provide such a stent wherein at least a portion of its wall structure is a hollow and inflatable wall fabricated of a semi-permeable membrane. Yet another object of the present invention is to provide such a stent wherein the hollow wall has disposed therein a hydrophilic material capable of absorbing a liquid to thereby increase the volume of the material and consequently inflate the wall. Still another object of the present invention is to provide such a stent wherein the hydrophilic material has therewith a drug. These and other objects of the invention will become apparent throughout the following description.

SUMMARY OF THE INVENTION

The present invention is a stent for placement within a body lumen and comprising a wall structure wherein at least a portion thereof is a hollow wall. The hollow wall has disposed therein a hydrophilic material which can be in the form of a gel, for example, which swells upon introduction of a liquid into the hollow wall to thereby achieve inflation thereof. The hollow wall with hydrophilic material therein is fabricated of a semi-permeable membrane whereby fluid from tissues surrounding the stent at the site of placement can pass through the membrane and swell the hydrophilic material to thereby inflate the wall. A therapeutic drug can be included with the hydrophilic material for release through the membrane at the site of stent placement. Examples of body lumens wherein a stent of the present invention can be employed include, but are not necessarily limited to, arteries, veins, urethral and ureteral ducts, biliary, hepatic and pancreatic ducts, bronchial, esophageal and bowel sections, sperm and fallopian ducts, eustachian tubes and lacrimal ducts. The entire wall structure of the stent can be a hollow wall, or the wall structure can incorporate both hollow and non-hollow portions such as hollow and solid fibers which are held together by being braided, woven or wound together.

The present invention provides a stent which, when placed and subsequently inflated, supports a lumen, yet, because the stent can be delivered to its site in a non-

inflated configuration, also provides consequent compact size during delivery to enhance placement within a lumen.

BRIEF DESCRIPTION OF THE DRAWINGS

Presently preferred embodiments of the invention are illustrated in the accompanying drawings in which:

FIG. 1 is a perspective view of a tubular stent, partially in section, whose entire wall structure is a hollow wall comprising an inflatable balloon;

FIG. 2 is an elevation view of a second embodiment of a tubular stent, partially in section, whose entire wall structure is a hollow wall comprising braided inflatable fibers;

FIG. 3 is an elevation view of a third embodiment of a tubular stent, partially in section, whose wall structure comprises a hollow wall portion of inflatable fibers and a solid wall portion of solid fibers, with both hollow and solid fibers braided together; and

FIG. 4 is a perspective view of a fourth embodiment of a stent, partially in section, whose entire wall structure is a hollow wall comprising an inflatable spiral.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

Referring to FIG. 1, a tubular stent 10 for placement within a body lumen is illustrated. The entire wall structure of the stent 10 is a hollow and inflatable wall 12 comprising a balloon 18 having a plurality of radial openings 16 therethrough to facilitate tissue ingrowth when the stent 10 is in place within a body lumen. The wall 12 is fabricated of a semi-permeable membrane whose construction is exemplified by polymers that can be formed into semi-permeable membranes as known in the art and capable of withstanding suitable inflation pressure. Non-limiting examples include polyamides, polyesters, polyurethanes, and ethylene vinyl alcohol. The stent 10 has disposed within its hollow wall 12 a hydrophilic material 32 which is capable of absorbing or attracting a liquid via osmotic dilution to thereby increase the volume of or pressure exerted by material 32. This hydrophilic material 32 can be any bio-compatible agent that will drive an osmotic pressure. Examples include, but are not limited to, inorganic salts, organic salts, sugars, poly saccharides, polymeric hydrogels, or amphoteric molecules. One preferred material is a hydrogel such as polyvinyl alcohol.

In use, the stent 10 is first positioned in a non-inflated state at the desired site within the body lumen by usual and appropriate delivery means such as an appropriately-sized catheter (not shown). This position is maintained by the delivery means at the site of desired placement for a period of time sufficient to permit the diffusion of an adequate amount of surrounding tissue fluids into the wall 12 to thereby swell the hydrophilic material 32 and inflate the stent 10 so that it independently remains in place by impinging on the interior lumen wall. Of course, the semi-permeable membrane employed to fabricate the wall 12 must be of sufficient strength to resist rupture from the pressure there within created by the expanded hydrophilic material. Ingrowth of tissue eventually occurs through the radial openings 16.

The stent 10 can also be employed as a time-release drug delivery device. In particular, a drug can be disposed with the hydrophilic material 32, either as a separate component or blended therewith. The drug then will be released into the surrounding tissues through the

semi-permeable membrane over a period of time. Of course, the drug so included is provided in an appropriate concentration, and may be with a carrier as necessary, to achieve the release rate desired. Additionally, the molecular weight of the drug should be lower than that of the hydrophilic material. One example of such a drug is piroxicam, commercially available as Feldene, manufactured by Pfizer Inc., New York, N.Y., present in an amount of about 20 to 500 mg per stent. The drug can be a separate component, or it can be included within the hydrophilic material by mixing it with or dissolving it into a solution of the hydrophilic material **32** for subsequent timed-release from the stent **10** for therapeutic efficacy. Of course, different drugs can be employed for different stent applications. Non-limiting examples of such drugs include anti-thrombic drugs for cardiovascular applications, anti-calcification drugs for urinary treatment, and anti-inflammatory or growth suppressing drugs for suppression of biologic response to stenting or balloon angioplasty.

The stent **10** can be constructed by providing two concentric tubular membranes whereby the inner surface of the outer membrane and the outer surface of the inner membrane define the inner wall surfaces of the hollow structure. Gel is introduced between the two membranes, after which a membrane sealing process as known in the art seals the ends of the stent **10** and concurrently cuts and seals the radial openings **16**.

FIG. **2** illustrates a second embodiment of a tubular stent **20** for placement within a body lumen. The entire wall structure of the stent **20** is a hollow and inflatable wall **24** comprising a plurality of braided hollow fibers **26**. While substantially the entire wall structure can comprise a plurality of braided hollow fibers **26** as shown in FIG. 2, a tubular stent **40** as illustrated in FIG. 3 can be constructed so that only a portion of the wall **44** comprises hollow fibers **26**. Thus the hollow fibers **26** of the stent **40** are braided with solid fibers **28**. A plurality of radial openings **29** extend through the respective walls **24, 44** to facilitate tissue ingrowth when a stent **20, 40** is in place within a body lumen. As with the balloon **18** of the stent **10** shown in FIG. **1**, the hollow fibers **26** of the stent **20, 40** are fabricated of a semi-permeable membrane whose construction is exemplified by polymers that can be formed into semi-permeable membranes as known in the art. Non-limiting examples likewise include polyamides, polyesters, polyurethanes, and ethylene vinyl alcohol. The hollow fibers **26** have disposed therein a hydrophilic material, as described above in relation to FIG. **1**, which is capable of absorbing a liquid to thereby increase the volume of the material and accomplish its inflation of the fibers **26**. Also, as earlier described, the hydrophilic material can have therewith a drug which will be released into the surrounding tissues through the semi-permeable membrane of the fibers **26** over a period of time.

The stent **20, 40** is positioned as described above in relation to FIG. **1** at its desired site within the lumen. Likewise, this position is maintained by the delivery means at the site of desired placement for a period of time sufficient to permit the diffusion of an adequate amount of surrounding tissue fluids into the fibers **26** to thereby swell the hydrophilic material and inflate the stent **20, 40** so that it independently remains in place by impinging on the interior lumen wall. Of course, the semi-permeable membrane employed to fabricate the hollow fibers **26** must be of sufficient strength to resist rupture from the pressure there within created by the expanded hydrophilic material. Tissue ingrowth occurs through the radial openings **29**.

One manner of constructing the stents **20**, here described can be employment of solvent casting techniques as known in the art. Thus, for example, an appropriately-shaped die is provided whereby a solution of a polymer is pumped from one portion of the die to form a hollow wall. Simultaneously, a hydrophilic material such as a gel is pumped from another portion of the die central to the polymer solution. When the polymer solution and gel reach a coagulation bath provided in such solvent casting, the gel is surrounded by the polymer as the structure becomes set. Alternatively, of course, the gel can be added under pressure into a length of fiber after which the fiber end is sealed.

FIG. **4** illustrates a fourth embodiment of a stent **50** whose entire wall structure is a hollow wall **52**. In particular, the stent **50** has a hollow and inflatable wall **52** comprising a balloon **54** having a spiral configuration when inflated as shown, yet can be delivered to a site within a lumen in a non-inflated, straightened configuration. As with the stents described in FIGS. **1–4**, the wall **52** of the stent **50** is fabricated of a semi-permeable membrane whose construction is exemplified by polymers that can be formed into semi-permeable membranes as known in the art. Non-limiting examples likewise include polyamides, polyesters, polyurethanes, and ethylene vinyl alcohol. The wall **52** has disposed therein a hydrophilic material, as described above in relation to FIG. **1**, which is capable of absorbing a liquid to thereby increase the volume of the material and accomplish inflation. At least a portion of the wall **52** can be reinforced with a fiber reinforcement **56** such as a polyester, nylon, or polypropylene, and preferably a polyester. One manner of providing the reinforcement **56** to the wall **52** during manufacture is to braid fibers around the structure and then apply an overcoat of the semi-permeable membrane. Such reinforcement, of course, provides a greater strength to the stent **50**.

The hollow wall **52** has disposed therein a hydrophilic material, and the stent **50** is positioned as described above in relation to FIGS. **1–3** at its desired site within the lumen. This position is maintained by the delivery means at the site of desired placement for a period of time sufficient to permit the diffusion of an adequate amount of surrounding tissue fluids into the wall **52** to thereby swell the hydrophilic material and inflate the stent **50** so that it assumes its spiral configuration and independently remains in place by impinging on the interior lumen wall. Of course, the semi-permeable membrane employed to fabricate the inflatable wall **52** must be of sufficient strength to resist rupture from the pressure there within created by the expanded hydrophilic material.

The stent **50** shown in FIG. **4** can also be employed as a time-release drug delivery device. In particular, a drug can be disposed with the hydrophilic material as described above within the wall **52**, and will be released into the surrounding tissues through the semi-permeable wall structure over a period of time.

While illustrative and presently preferred embodiments of the invention have been described in detail herein, it is to be understood that the inventive concepts may be otherwise variously embodied and employed and that the appended claims are intended to be construed to include such variations except insofar as limited by the prior art.

What is claimed is:

1. A stent for placement within a body lumen. The stent comprising a wall structure wherein at least a portion thereof is a closed hollow wall having a plurality of radial openings therethrough, fabricated from a semi-permeable membrane, and wherein the hollow wall has disposed therein a hydrophilic material capable of absorbing a liquid to thereby increase the volume of said material.

2. A stent as claimed in claim 1 wherein the hydrophilic material is a gel.

3. A stent as claimed in claim 1 wherein the configuration thereof is tubular.

4. A stent as claimed in claim 3 wherein the stent is a balloon.

5. A stent as claimed in claim 1 wherein the hydrophilic material has disposed therewith a drug.

6. A stent for placement within a body lumen, the stent comprising a wall structure wherein at least a portion thereof is a hollow wall fabricated from hollow closed fibers which are constructed of semi-permeable membranes and held together by being braided, woven or wound together, and wherein the hollow fibers have

disposed therein a hydrophilic material capable of absorbing a liquid to thereby increase the volume of said material.

7. A stent as claimed in claim 6 wherein the hydrophilic material is a gel.

8. A stent as claimed in claim 6 wherein the hydrophilic material has disposed therewith a drug.

9. A stent for placement within a body lumen, the stent having a spiral configuration when inflated and comprising a wall structure wherein at least a portion thereof is a closed hollow wall, fabricated from a semi-permeable membrane, and wherein the hollow wall has disposed therein a hydrophilic material capable of absorbing a liquid to thereby increase the volume of said material.

10. A stent as claimed in claim 9 wherein the hydrophilic material has disposed therewith a drug.

11. A stent as claimed in claim 9 wherein at least a portion of the hollow wall is reinforced.

12. A stent as claimed in claim 9 wherein the stent is a balloon.

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